EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ILLUMINA, INC. AND ILLUMINA CAMBRIDGE, LTD. Plaintiffs, v. ELEMENT BIOSCIENCES, INC. Defendant.	C.A. No. 1:25-cv-00602-RGA **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Illumina, Inc. and Illumina Cambridge, Ltd. (together, "Illumina"), by and through their undersigned attorneys, for their Complaint against Defendant Element Biosciences, Inc. ("Element") allege, upon knowledge with respect to its own and publicly available information and upon information and belief as to the acts of others, as follows:

NATURE OF THE ACTION

1. This is an action about Element's unauthorized use of Illumina's patented innovations in the automation of genetic sequencing and its attempt to profit from Illumina's extensive investment in research and

development that led to those inventions. Illumina seeks damages for Element's past infringement of its patents and an injunction to preclude Element's continued use of Illumina's patented inventions.

2. Specifically, this is an action for infringement under 35 U.S.C. § 271(a) and § 271(b) of U.S. Patent No. 12,151,241 (the "'241 Patent"); U.S. Patent No. 8,951,781 (the "'781 Patent"); U.S. Patent No. 11,117,130 (the "'130 Patent"), U.S. Patent No. 11,697,116 (the "'116 Patent"), U.S. Patent No. 12,251,702 (the "'702 Patent"), U.S. Patent No. 12,325,028 (the "'028 Patent") and U.S. Patent No. 12,397,301 (the "'301 Patent") (collectively, the "Patents-in-Suit"). Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." As detailed below, Element makes, uses, offers to sell and sells products that include the inventions Illumina patented in the Patents-in-Suit and induces its customers to infringe the Patents-in-Suit.

3. Illumina's patents are directed to genetic sequencing instruments (or "systems," as they are sometimes called in the Patents-in-Suit) and their associated "consumables," which include packages of chemical reagents and

other components that are used to perform sequencing using the patented systems. The patented systems are used to perform genetic sequencing by determining the "code" that makes up DNA and other genetic material.

4. Genetic sequencing systems are used by research organizations and hospitals to sequence DNA for many applications. For example, decoding an individual's DNA allows researchers to predict the likelihood that a person will develop certain diseases, diagnose previously hard to detect diseases that may be afflicting a person and—based on that genetic information—develop treatments for them. Genetic sequencing also allows scientists to research the underlying causes of certain diseases and develop more effective treatments for those diseases.

5. Illumina is a pioneer in genetic sequencing and has advanced the state of the art significantly over the last 25 years. When Illumina was founded in 1998, research institutions were engaged in a multinational campaign—the Human Genome Project—to sequence a single human genome. That effort cost $3 billion and took 13 years because—at the time—sequencing could only be performed by highly skilled scientists and at great time and expense. Illumina's innovations made sequencing more accessible by simplifying the sequencing workflow, reducing the cost of sequencing and automating many tasks. These benefits allowed sequencing to be used for more applications.

6. Through a series of innovations and investment, Illumina has continued to reduce sequencing costs and expand access to sequencing for more users. In 2011, Illumina introduced the MiSeq® instrument, which practices the inventions of many of the Patents-in-Suit. The MiSeq provided a low cost, personal, next-generation sequencing system that enabled users to perform a single sequencing run for only $400. For comparison, Illumina's first sequencer, the Genome Analyzer, which launched in 2007, cost $3,000 to run and generated less than a fifteenth of the data per run that could be generated by the MiSeq.

7. Through the innovations claimed in the Patents-in-Suit, Illumina turned a process conducted by specialist technicians that was time-consuming and error-prone into a reliable, fully automated endeavor that can be performed by someone with limited specialized training. These patents disclose and protect key innovations that made Illumina's sequencing machines so much more reliable, efficient and effective than prior systems. These innovations also dramatically increased the accessibility of sequencing. Both the affordable cost and the accessibility of the MiSeq made it the most popular instrument in Illumina history, expanding access to next-generation sequencing technology. In 2013—

only two years after launch—two thirds of readers surveyed by a popular genomics news site owned at least one MiSeq.[1]

8. Element does not have this history of innovation. It was formed by a group of former Illumina employees in 2017 to sell genetic sequencing systems that borrow heavily from Illumina's systems, including technologies that were developed while those Element employees were working at Illumina. To aid its "development" efforts, Element acquired one of Illumina's MiSeq sequencing instruments in 2019. With that machine in Element's hands, it is not surprising that Element's devices incorporate many of the patented innovations introduced in the MiSeq. Today, Element's sequencing instruments and consumables compete directly with Illumina's products.

9. Element seeks to use and profit from Illumina's innovations without compensating Illumina for its tremendous investment in research and development over many decades to create its groundbreaking genetic sequencing instruments. Illumina brings this action to hold Element accountable for its sale of systems claimed by the Patents-in-Suit and to end its infringement.

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[1] Ex. 1, Julia Karow, "In Sequence 2013 Survey: Illumina Pulls Further Ahead, Interest in Oxford Nanopore Remains High," genomeweb (Jan. 7, 2014), https://www.genomeweb.com/clinical-sequencing/sequence-2013-survey-illumina-pulls-further-ahead-interest-oxford-nanopore.

THE PARTIES

10. Plaintiff Illumina, Inc. is a Delaware corporation with its principal place of business at 5200 Illumina Way, San Diego, California 92122.

11. Illumina, Inc. researches and develops cutting edge genetic sequencing instruments and reagents and other products used in sequencing applications and sells them within the United States. Illumina, Inc. is the exclusive licensee of the Patents-in-Suit. Illumina, Inc.'s products include the MiSeq, MiniSeq®, NextSeq® and NovaSeq® systems.

12. Plaintiff Illumina Cambridge, Ltd. is a subsidiary of Illumina, Inc. and is organized and existing under the laws of England and Wales. Its principal place of business is 19 Granta Park, Great Abington Cambridge, Cambridgeshire CB21 6DF, United Kingdom.

13. Illumina Cambridge, Ltd. distributes the genetic sequencing products developed by Illumina, Inc. through a global network of channel partners and distributors, including Illumina, Inc. in the United States. Illumina Cambridge, Ltd. is the sole and exclusive owner of legal title to the Patents-in-Suit.

14. In recognition of its contributions to the industry, Illumina was inducted into the Small Business Innovation Research Hall of Fame in 2017. In 2020, the inventors of Illumina's sequencing technology received the Millennium Technology Prize. Illumina was listed as one of MIT Technology Review's

25 Smartest Companies in 2015; Forbes' Most Innovative Companies in 2016, 2017 and 2018; Fast Company's Most Innovative Companies in Biotechnology in 2017 and Most Innovative Health Companies in 2022 and TIME's 100 Most Influential Companies in 2021.

15. Defendant Element is a Delaware corporation having its principal place of business at 10055 Barnes Canyon Road, San Diego, California 92121.

16. Element was founded by former Illumina employees who, in their roles at Illumina, had extensive exposure to Illumina's patented technology. For example, Molly He, the co-founder and CEO of Element Biosciences, worked as Illumina's Senior Director of Scientific Research for eight years.

17. Element is headquartered near Illumina's former headquarters. Since its founding, Element has routinely hired Illumina employees.

18. Element recently introduced a series of instruments that use important features from Illumina's sequencing systems. Element markets these instruments under the name AVITI.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Element because Element is incorporated in the state of Delaware.

21. Venue is proper in this judicial district under 28 U.S.C. § 1400(b), because Element, as a Delaware corporation, is deemed to reside in this district.

FACTUAL BACKGROUND

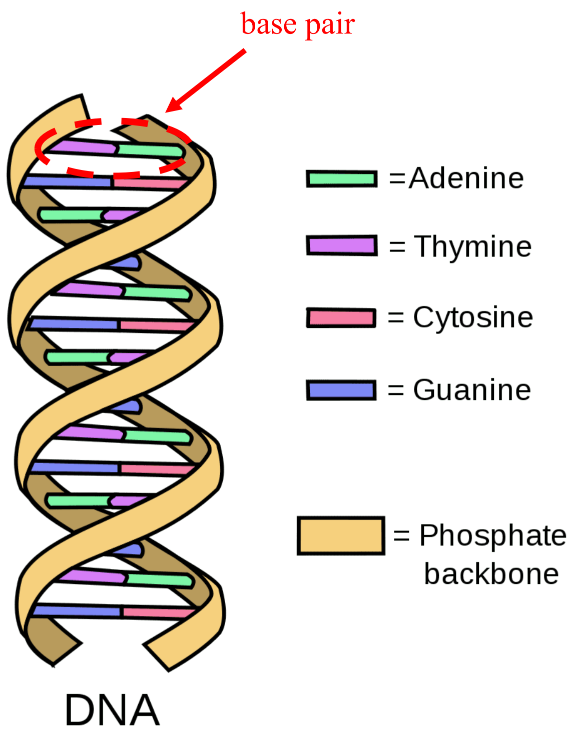
Basics of Genetic Sequencing

22. Genetic sequencing has numerous therapeutic, diagnostic and scientific applications. Sequencing has facilitated advances in many fields, including oncology, in the study of genetic and infectious diseases and in reproductive health. Genetic sequencing enables doctors to provide better care and personalized medicine for patients and helps researchers make advances in our understanding of evolution and biology.

23. Genetic sequencing is essentially the decoding of nucleic acids such as deoxyribonucleic acid or "DNA." DNA molecules in living organisms carry genetic information that enables those organisms to develop, function and reproduce. The genetic information in DNA is found in the specific and particular sequence of the units—called nucleotides—in a DNA strand. Those sequences function like a code that stores information. The code contains genes, specific sequences of DNA that enable organisms to make various proteins that perform

critical functions. Knowing the sequence of nucleotides in a DNA sample allows scientists to understand genetic diseases and to screen for fetal abnormalities and cancers.

24. The four nucleotide bases in DNA are cytosine, guanine, adenine and thymine, typically abbreviated as "C," "G," "A" and "T." Two strands of nucleotide bases intertwine to form the well-known DNA "double helix," shown below. To create the double helix, each nucleotide base in one strand pairs with a complementary nucleotide base on a second strand, creating a "base pair." Each base pair functions as a rung in the DNA "ladder."



25. Nucleotides may take any order within an individual strand of DNA, but each natural DNA nucleotide base correctly binds to only one specific

complementary natural DNA nucleotide base on the complementary strand: guanine correctly pairs with cytosine and adenine correctly pairs with thymine. Because of this complementarity, identifying the sequence of nucleotides in a strand of DNA reveals the sequence of nucleotides in its complementary strand.

26. Genetic sequencing technology can be used by scientists to identify the specific order of nucleotides in any strand of DNA, making the technology a powerful tool in genetic research.

Illumina's Innovations Revolutionized Genetic Sequencing

27. In the mid-2000s, the ability to perform genetic sequencing was limited to a small number of academic genome research centers. In 2003, the Human Genome Project—a collaboration across genome research centers in many countries—completed its 13-year campaign to sequence just one human genome at a total cost of about $3 billion. Because sequencing was so expensive and time-consuming, it could not be practically used in many settings, and the only customers for genetic sequencing were large research institutions. As described below, Illumina's innovations changed that by making sequencing faster and more affordable and increasing access to more users.

28. In 2007, Illumina acquired a startup called Solexa, which had developed a method of sequencing known as "sequencing-by-synthesis." Sequencing-by-synthesis belongs to a class of high-throughput sequencing

techniques collectively called next-generation sequencing ("NGS"). At the time Illumina acquired Solexa, sequencing-by-synthesis was considered an inflexible process that could not be easily adapted and was expected to hit a "ceiling"—after which no significant further improvements would be possible—within a few years. Upending these expectations, however, Illumina improved both the chemistry of the sequencing process and the mechanisms of sequencing instruments to the point that Illumina's NGS is more accurate, cheaper and faster than other NGS technologies. One key to Illumina's superiority is that unlike the type of sequencing that had been used by the researchers in the Human Genome Project, in which nucleotides in a target DNA sample were painstakingly sequenced a handful of strands at a time, Illumina's NGS allows millions of different portions of the same DNA sample to be sequenced simultaneously in a "massively parallel" fashion.

29. At a high level, the sequencing techniques used by Illumina's instruments (and Element's infringing instruments) rely on the complementary nature of DNA nucleotide bases to sequence the target DNA sample. As part of the sequencing workflow, the following steps (among others) are typically performed:

- The DNA sample of interest is fragmented into smaller pieces and each is bound to a "flow cell," where the sequencing is performed in the sequencing instrument. The flow cell is a microfluidic device specially designed to enable the flow of fluids through one or more channels to react with the sample.

- The sequencer introduces several liquids known as "reagents" to the flow cell in succession. These reagents are designed to cause specific chemical reactions within the flow cell.

- To determine the order of nucleotides in the DNA fragments, a light source illuminates portions of the flow cell, which excites fluorescently-tagged sequencing reagents and causes them to emit fluorescent signals. An imaging device captures these emitted fluorescent signals, which are correlated to different nucleotides, allowing the sequencer to determine the order of the nucleotides.

- The steps of adding reagents, stimulating the flow cell with excitation light and using the imaging device to determine which fluorescent signals are emitted are repeated many times, thereby determining the order of the nucleotides in the DNA samples.

Drawbacks of Early NGS Technology

30. Early sequencing technologies required considerably more manual effort than Illumina's MiSeq and MiniSeq instruments, each of which practice inventions of the Patents-in-Suit.

31. Early NGS systems required highly trained personnel and time-consuming processes to minimize user error. For instance, the Genome Analyzer—which was launched in 2007—required the user to apply immersion oil between the flow cell and the face of a prism, manually align the flow cell and clamp on fluidic manifolds to secure the flow cell. Each step introduced a possibility of user error. To name just a few possibilities, misaligning the flow cell could lead to the reagents leaking during synthesis and/or could introduce bubbles

into the flow cell that could obstruct imaging, while adding excess oil could cause the oil to drip onto other components, in addition to generally being a messy process. Flow cell misalignment also potentially affected the positioning of the flow cell for imaging, requiring fixes to compensate for potential imaging misalignment, which could otherwise impact the sequencing process.

32. Such errors had expensive consequences. The samples and reagents used for performing sequencing are costly. Leakages wasted samples that had been painstakingly isolated by technicians as well as precious reagents and required researchers to restart their sequencing runs, losing valuable time. And if the instrument components were not positioned correctly, then the sequencing data obtained from a run could contain errors, requiring the sequencing run to be repeated, wasting samples and reagents and again losing time.

Illumina's Innovations in Instrument Design

33. The Patents-in-Suit solve the problems of earlier systems by removing the need to rely on the user's ability to precisely place their samples and reagents into the sequencing instrument. For example, aspects of the Patents-in-Suit are directed to improved methods for securing the flow cell containing the DNA sample of interest in the correct position for sequencing, while other aspects are directed to improving the mechanisms for securing the sequencing reagents and automatically distributing them to the flow cell during sequencing. No prior

system handled the alignment of the sequencing flow cell as claimed in the Patents-in-Suit.

34. The innovations of the patented systems eliminate the manual alignment of the flow cell required by prior systems and instead allow a user to insert and secure a flow cell in a device holder and have it automatically aligned for sequencing. Specifically, the flow cell can be automatically aligned using an actuator system and fixed in place using a rotatable cover so it can be accurately imaged by the optical sensor over repeated cycles of sequencing. The patented systems also enable further improvements in establishing the fluidic connection between the inlet and outlet ports of the flow cell and the fluidic ports of the instrument.

35. Other Patents-in-Suit further reduce the need for human intervention during the sequencing process with improvements to the fluid storage system of the sequencing instruments. These patents contain innovations that allow a user to insert a tray containing reagents into a temperature-controlled enclosure on the instrument and have "sipper tubes" or "sippers" automatically descend in an accurate, reliable and repeatable manner into the tray to extract reagents and deliver them to the flow cell. The sippers can then be automatically withdrawn from the trays for safe removal of the tray from the instrument.

36. Illumina designs and sells instruments that practice the patented inventions. Among them are the MiSeq, which enabled users to finish sequencing runs in just eight hours from the first step of sample preparation to the completed result, including only twenty minutes of "hands-on time." Since its release, Illumina has continued to make improvements to the MiSeq system, and the instrument can now complete a sequencing run of 850 million base pairs in only five and a half hours, or as many as 15 billion base pairs when using Illumina high-output consumables. The MiSeq is shown below.

Height
52.3 cm
(20.6 in)
Depth
56.5 cm (22.2 in)
Width
68.6 cm (27 in)

("MiSeq Sequencing System," Illumina, https://sapac.illumina.com/systems/sequencing-platforms/miseq.html.)

37. The combination of innovations protected by the Patents-in-Suit made the MiSeq a hugely successful instrument that could perform lab-scale sequencing runs faster and more cheaply than its predecessors.

38. Illumina's MiniSeq sequencer also practices inventions of the Patents-in-Suit. Released in 2016, the MiniSeq, like the MiSeq, is designed for "load and go" use, minimizing manual preparation, errors and inconsistencies in sequencing. The MiniSeq can sequence up to two billion base pairs in five hours, not including the time to prepare the sample library. The MiniSeq is shown below.

MiniSeq
Welcome to MiniSeq
illumina
Height:
30.5 cm
(12 in)
Depth: 33 cm (13 in)
Width: 42.5 cm (16.8 in)

("MiniSeq Sequencing System," Illumina, https://www.illumina.com/systems/sequencing-platforms/miniseq.html.)

39. Illumina spent decades and invested millions of dollars in improving sequencing technology and the sequencing process. In 2007, the year that Illumina launched the Genome Analyzer, it spent $65 million on research and

development. Since then, Illumina has greatly increased the resources it has directed toward innovation. Its research and development expenses grew to $167 million in 2011 and $1.2 billion in 2024.

40. Through its many technological innovations, such as those protected by the Patents-in-Suit, Illumina has made it easier to sequence genetic material without the supervision of highly trained lab technicians. This achievement allows laboratories to sequence more samples at a lower price and has expanded the types of institutions that can perform sequencing.

41. Illumina's innovations have made sequencing faster, easier, more accurate and more reliable. Among other advantages of Illumina's NGS, Illumina's instruments have lower sample input requirements, higher accuracy and the ability to detect even rarer genetic variants than was previously possible.

42. Many scientific and medical advancements have been made possible because of Illumina's innovations. Illumina's NGS technology has so significantly reduced the duration and cost of sequencing that it is now feasible in clinical settings. Early NGS instruments could not be used in the clinical setting because the instruments were too complex and yielded insufficiently reproducible results to obtain FDA approval. Illumina's MiSeq instrument—the first of Illumina's instruments to incorporate innovations of the Patents-in-Suit—was the

first sequencing instrument of any kind to be approved by the FDA to perform diagnostic tests (under the name "MiSeqDx") in a clinical setting.

43. Illumina's genetic sequencing technology has been used for many applications, including to enable researchers to identify cellular biomarkers associated with the regulation of cancer genes and treatment resistance. Illumina's sequencing methods can also be used to predict therapeutic responses to targeted therapies and personalized anticancer vaccines.

44. Illumina's genetic sequencing technology also allows pregnant women to screen their unborn children for genetic conditions. Genetic-sequencing-based techniques rely on tiny amounts of fetal DNA circulating in a pregnant woman's blood, known as circulating cell-free fetal DNA. Illumina's NGS platforms enable highly accurate testing of the fetal genome from only a small sample of fetal DNA from the mother's bloodstream.

THE PATENTS-IN-SUIT

45. The '241 Patent (attached as Exhibit 2), entitled "Systems, Methods, and Apparatuses To Image a Sample for Biological or Chemical Analysis," was filed on February 23, 2024, and duly and lawfully issued on November 26, 2024. The '241 Patent names Erik Williamson, Bryan Crane, Patrick Leung, Drew Verkade and Mark T. Reed as inventors.

46. The ’781 Patent and Certificate of Correction (attached as Exhibit 3), entitled “Systems, Methods, and Apparatuses To Image a Sample for Biological or Chemical Analysis,” was filed on October 14, 2011, and duly and lawfully issued on February 10, 2015. The ’781 Patent names Erik Williamson, Bryan Crane, Patrick Leung, Drew Verkade and Mark T. Reed as inventors.

47. The ’130 Patent and Certificate of Correction (attached as Exhibit 4), entitled “Systems, Methods, and Apparatuses To Image a Sample for Biological or Chemical Analysis,” was filed on May 14, 2020, and duly and lawfully issued on September 14, 2021. The ’130 Patent names Erik Williamson, Bryan Crane, Patrick Leung, Drew Verkade and Mark Reed as inventors.

48. The ’116 Patent and Certificate of Correction (attached as Exhibit 5), entitled “Systems, Methods, and Apparatuses To Image a Sample for Biological or Chemical Analysis,” was filed on April 5, 2022, and duly and lawfully issued on July 11, 2023. The ’116 Patent names Erik Williamson, Bryan Crane, Patrick Leung, Drew Verkade and Mark T. Reed as inventors.

49. The ’702 Patent and Certificate of Correction (attached as Exhibit 6), entitled “Flowcell Cartridge with Floating Seal Bracket,” was filed on September 6, 2024, and duly and lawfully issued on March 18, 2025. The ’702 Patent names David Elliott Kaplan, Anthony John de Ruyter, Richard Alan Kelley and Ashish Kumar as inventors.

50. The ’028 Patent (attached as Exhibit 7), entitled “Flowcell Cartridge with Floating Bracket,” was filed on February 11, 2025, and duly and lawfully issued on June 10, 2025. The ’028 Patent names David Elliott Kaplan, Anthony John de Ruyter, Richard Alan Kelley and Ashish Kumar as inventors.

51. The ’301 Patent (attached as Exhibit 8), entitled “Flowcell Cartridge with Floating Bracket,” was filed on May 5, 2025, and duly and lawfully issued on August 26, 2025. The ’301 Patent names David Elliott Kaplan, Anthony John de Ruyter, Richard Alan Kelley and Ashish Kumar as inventors.

ELEMENT’S USE OF ILLUMINA TECHNOLOGY

52. Element was founded in 2017 by ex-Illumina employees who had helped develop Illumina’s NGS technology. Element’s founder and CEO, Molly He, was Illumina’s former Senior Director of Scientific Research. The other two founders of Element are Mike Previte, a former Illumina Associate Principal Scientist, who is now Element’s CTO, and Matt Kellinger, a former Illumina Staff Scientist, who is currently Element’s head of biochemistry.

53. Element hired other employees from Illumina who have extensive information about Illumina’s genetic sequencing products. Examples, apart from Elements’ founders, are Logan Zinser, Illumina’s former Senior Director of Finance, who joined Element in 2020 and is now Element’s Chief Financial Officer, and Yaron Hakak, Illumina’s former Director of Corporate and

Business Development, who joined Element in 2023 and is now Element's Senior Vice President of Corporate and Business Development. In 2021, Element hired Richard Kelley, a former Senior Staff Development Engineer at Illumina, who then served as a Mechanical Engineer at Element for one and a half years.

54. These former employees (including all three of Element's founders) are familiar with the MiSeq system, which practices innovations claimed by the Patents-in-Suit, from their work at Illumina. They are also familiar with Illumina's efforts to patent its technology, including the innovations practiced by the MiSeq system. Richard Kelley, who claims to have managed the mechanical engineering instrument and consumables development team for the AVITI DNA sequencer while at Element, touts his past experience with the MiSeq flow cell latch design and his experience as a key architect of the overall MiniSeq mechanical layout. Further, Kelley is an inventor of three of the Patents-in-Suit: the '702 Patent, the '028 Patent and the '301 Patent.

55. Even as Element touted its promise to "disrupt" the genetic sequencing space, it operated in "stealth mode" for the first five years of its existence. In 2019, while secretly developing its own NGS instruments, Element purchased a MiSeq sequencing instrument from Illumina, as well as kits containing the MiSeq sequencing reagents and consumables. Element then acquired Loop Genomics, a sequencing company that had previously purchased a MiniSeq

sequencing instrument. Element then possessed both Illumina's MiSeq and MiniSeq systems and incorporated their patented innovations into its infringing sequencing instruments.

56. Until 2021, Element refused to disclose how key aspects of its technology worked, repeatedly refusing requests for comment from interested press. Even after emerging from stealth mode, Element has issued only vague platitudes, like its goals of "improving signal-to-noise ratio at every stage in the sequencing process" and "decentralizing" sequencing (things that Illumina's sequencing instruments already do).

57. Element was aware of Illumina's portfolio of MiSeq patents at least through its purchase of the MiSeq instrument. The instrument that Element acquired was affixed with a label referring to Illumina's virtual patent marking website, which, at the time of Element's purchase, identified the '781 Patent as practiced by the MiSeq instrument. Other Patents-in-Suit in that patent family, namely, the '241 Patent, '130 Patent and '116 Patent, subsequently issued and were added to the virtual marking website.

58. Further evidencing Element's knowledge of the Patents-in-Suit and its infringement, in May 2021, Element requested that Illumina grant it a broad covenant not to sue on any patents in Illumina's portfolio. Illumina declined that request.

59. In 2022, Element finally revealed the product it was developing: an NGS machine that practices many of the innovative features of Illumina's patented MiSeq and MiniSeq products—the same products that Element had acquired. As described below, Element's AVITI sequencers are highly similar to Illumina's sequencing instruments and practice every limitation of the asserted claims of the Patents-in-Suit.

Element's Infringement of Illumina's Patents

60. Element designs, manufactures, uses and sells the AVITI line of sequencing instruments. It launched the AVITI sequencer in 2022 and the AVITI LT sequencer in 2023. In 2023, Element claimed that it exceeded 160 orders for its infringing devices and associated products, generating more than $25 million in revenue.

61. In April 2024, Element announced the AVITI24 sequencer (collectively with the AVITI and AVITI LT, the "AVITI Systems"). Element is taking preorders for the AVITI24 at the pre-order price in the U.S. of $424,000.

62. Element claims that the AVITI sequencer is "a next-generation sequencing (NGS) system that provides scalable solutions for high-quality sequencing." (Ex. 9, AVITI System User Guide at 6.) The AVITI system is shown below:

(Ex. 10, AVITI System Specification Sheet (2024) at 1.)

63. Element describes the AVITI LT as "a low-throughput version of AVITI." (Ex. 11, Element, "Discover the AVITI family," https://www.elementbiosciences.com/products/aviti/family.) The AVITI LT System is the same physical machine as the AVITI, but with software limitations that prevent the AVITI LT from being used for the higher-throughput use cases for which the AVITI system can be used. Element touts that the AVITI LT System offers the "flexibility to upgrade to a full-throughput AVITI with a simple software update." (Ex. 12, Element, "AVITI Products," https://www.elementbiosciences.com/products/aviti#aviti-lt.) Because the two systems are essentially identical, the AVITI LT infringes the Patents-in-Suit in the same manner as the AVITI System.

64. Element describes the AVITI24 system as a benchtop platform for "high-quality, affordable sequencing and in situ multiomics." (Ex. 13,

Element, "AVITI24," https://www.elementbiosciences.com/products/aviti24.) Like the AVITI, the AVITI24 uses a dual flow cell design. The AVITI24 system is shown below.

AVITI 24
AVITI

(Ex. 14, AVITI24 System Specification Sheet at 1.)

65. Element sells several lines of products that include flow cells for use in the AVITI Systems. These products include the Cloudbreak and Trinity lines of sequencing kits. Element also sells the Teton slide and flow cell assembly kit, which include components that can be assembled into a flow cell for use in the AVITI24.

66. The Cloudbreak line of sequencing kits includes the Cloudbreak Freestyle sequencing kits, the Cloudbreak sequencing kits and

Cloudbreak UltraQ sequencing kits (collectively, the "Cloudbreak Sequencing Kits"). The Cloudbreak Sequencing Kits are compatible with all of the AVITI Systems. (Ex. 15, Cloudbreak Sequencing User Guide at 1 (stating that the guide is for use with the Cloudbreak, Cloudbreak Freestyle and Cloudbreak UltraQ sequencing kits and the AVITI, AVITI LT and AVITI24 systems).) Each of the Cloudbreak Sequencing Kits include flow cells, plastic cartridges and consumables for use with the AVITI Systems "to sequence libraries on an AVITI System or an AVITI24 System." (Ex. 15, Cloudbreak Sequencing User Guide at 4.) The Cloudbreak Sequencing Kits each contain an equivalent flow cell and plastic cartridge, which is shown below.

SN 2302503558
REF 810-00002
LOT 2303020002
Cloudbreak
Element
Biosciences

(Ex. 16, "Cloudbreak™ Sequencing Kits," https://www.elementbiosciences.com/products/cloudbreak.)

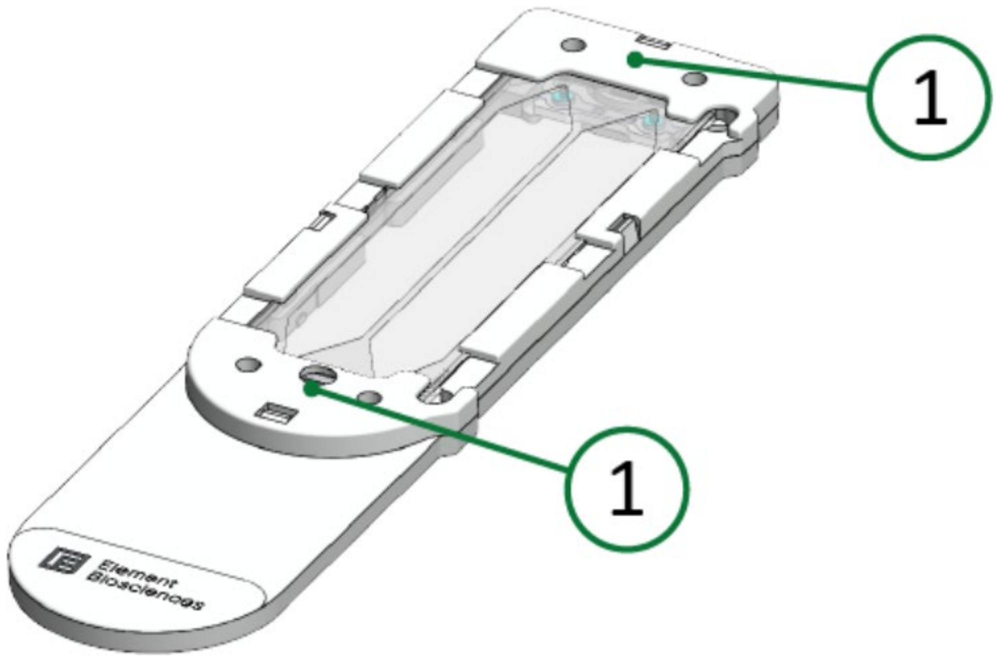
67. Element's Cloudbreak Freestyle sequencing kits (which include flow cells and plastic cartridges) for the AVITI are designed so that sample libraries prepared for use on Illumina's sequencing systems can be used directly with the AVITI. (Ex. 17, Element AVITI System Brochure at 5.)

68. Element's Trinity sequencing kits are used for targeted sequencing. The Trinity sequencing kits are compatible with all of the AVITI Systems. (Ex. 18, Trinity Sequencing User Guide at 1 (stating that the guide is for use with Trinity sequencing kits and the AVITI, AVITI LT and AVITI24 systems).) Each of the Trinity sequencing kits includes a flow cell, a buffer bottle, a reagent cartridge, the library loading buffer and a sequencing reagent. (Ex. 18, Trinity Sequencing User Guide at 4–5.) The Trinity sequencing kits each contain the same flow cell and plastic cartridge, which are shown below.

SN 2417420279
REF 810-00015
LOT 2401040001
Trinity Flow Cell
Element Biosciences

(Ex. 19, "Trinity," https://www.elementbiosciences.com/products/trinity.)

69. Element's Teton slide and flow cell assembly kits contain components that the user can assemble into a flow cell and plastic cartridge. Specifically, a flow cell may be assembled using the glass slide in the Teton slide kit and other components in the Teton flow cell assembly kit using assembly tools called the Teton flow cell aligner and Teton flow cell sealer. (Ex. 20, Teton CytoProfiling User Guide at 19.) A diagram of the assembled flow cell is shown below.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotations in original).)

70. Element's Teton kits are compatible with the AVITI24. (Ex. 20, Teton CytoProfiling User Guide at 1 (stating that the guide is for use with Teton CytoProfiling kits and the AVITI24).) Specifically, Element's Teton kits are consumables for use with the AVITI24 to "perform[] avidite base chemistry (ABC) sequencing within cell samples to detect numerous cellular RNAs and proteins." (Ex. 20, Teton CytoProfiling User Guide at 5.)

71. The Cloudbreak Sequencing Kits, the Trinity sequencing kits, and the Teton slide and flow cell assembly kits (collectively, the "Element Sequencing Kits") all include a flow cell and a plastic cartridge with equivalent designs (or, in the case of the Teton slide and flow cell assembly kits, the

components to assemble a flow cell and a plastic cartridge with the same design). Accordingly, Illumina's allegations regarding the flow cell and the plastic cartridge described in the AVITI Systems or in any of the Element Sequencing Kits apply equally to the flow cell and the plastic cartridge contained in the other products.

72. Element has infringed and continues to infringe the Patents-in-Suit by making, using, offering to sell and selling within the United States the AVITI Systems and Element Sequencing Kits.

COUNT I: INFRINGEMENT OF THE '241 PATENT

73. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

74. Element has infringed at least Claims 1, 2–3, 7–12, 14, 15–16, 17 and 18–20 of the '241 Patent in violation of 35 U.S.C. § 271(a), by making, using, offering to sell and selling within the United States the inventions claimed in the '241 Patent.

75. Independent Claim 1 of the '241 Patent recites:

> A system comprising:
>
> an optical system comprising an excitation light source, an imaging detector, and an optical train;
>
> a device holder to orient a fluidic device for imaging by the optical system, the fluidic device comprising a flow cell, the device holder comprising:

> a support structure including a loading region to receive the fluidic device, the loading region including a base surface to have the fluidic device positioned thereon, and
>
> a rotatable cover that is coupled to the support structure and moveable about an axis between an open position and a closed position, the cover movable to the open position to permit the fluidic device to be inserted into and removed from the loading region and movable to the closed position to secure the fluidic device within the loading region for imaging, wherein the cover is biased toward the open position, and
>
> a latch to releasably hold the cover in the closed position;
>
> a fluid storage system comprising:
>
> an enclosure having a cavity,
>
> a door openable to provide access to the cavity,
>
> a transport platform holding an array of sipper tubes, each sipper tube of the array of sipper tubes includes a distal portion positioned to be inserted into a component well of a reaction component tray within the cavity, and
>
> a drive motor operatively coupled to the transport platform, the transport platform moveable by the drive motor to position the array of sipper tubes at least partially within the cavity; and
>
> a casing enclosing the optical system, the device holder, and the fluid storage system therein.

(Ex. 2, ’241 Patent at 53:36–54:4.)

76. “A system comprising.” The AVITI Systems each are systems as recited in Claim 1 of the ’241 Patent.

77. “The AVITI System is a next-generation sequencing (NGS) system” that uses a dual-flow cell system. (Ex. 9, AVITI System User Guide at 6.) As shown below, the AVITI Specification Sheet describes the AVITI system as

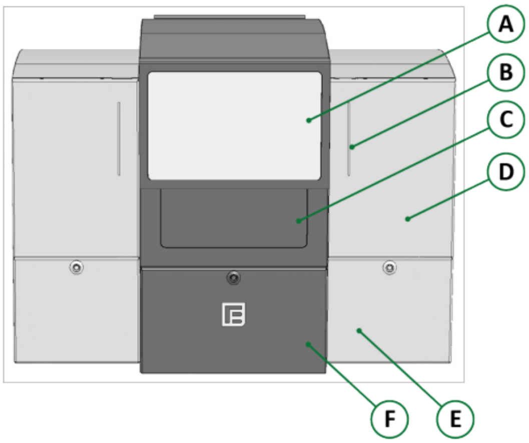
including a touchscreen monitor (A), nests holding two flow cells (B), an LED display (C), reagents (D) and waste bottles (E):

A
B
C
D
E
AVITI

(Ex. 21, AVITI System Specification Sheet (2023) at 4.)

78. The AVITI LT system is the same physical machine as the AVITI, but with software limitations that prevent the AVITI LT from being used for higher-throughput use cases. The AVITI LT has no documentation or manuals of its own, and instead directs the user to the documentation to the AVITI instrument. (*See, e.g.*, Ex. 9, AVITI System User Guide at 1 (stating that the guide is for use with both the "AVITI System" and the "AVITI System LT").)

79. The AVITI24 system is a "multidimensional genomics instrument." (Ex. 22, AVITI24 System User Guide at 6.) As shown below, the AVITI24 includes a touchscreen, a nest bay and pump, reagent and waste bays:



A Touchscreen monitor
B Lightbars
C Nest bay with automated nest door
D Pump bays hold fluidic pumps
E Reagent bays hold reagents for each run
F Waste bay holds waste bottles

(Ex. 22, AVITI24 System User Guide at 7.)

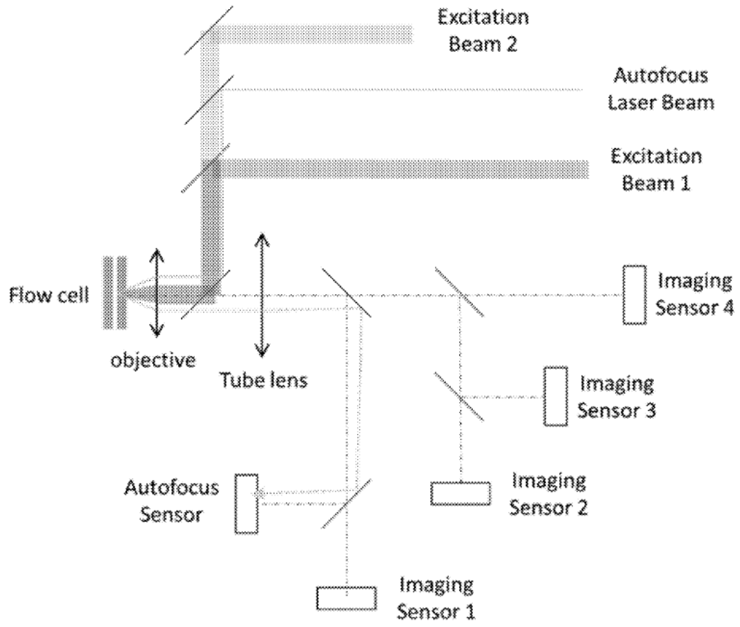
80. "an optical system comprising an excitation light source, an imaging detector, and an optical train." Element's AVITI Systems include an optical system with an excitation light source, an imaging detector and an optical train (*i.e.*, an arrangement of optical components, such as lenses and mirrors to guide the light), as recited in Claim 1 of the '241 Patent. A 2023 publication authored by current and former employees of Element Biosciences describes these components:

> Avidity sequencing was performed on the AVITI commercial sequencing system. Briefly, the instrument is a four-color optical system with two ***excitation lines*** of approximately 532 and 635 nm. The four-color system is created using an objective lens, multiple ***tube lenses*** and multiple ***cameras for simultaneous imaging*** of four spectrally separated colors.

(Ex. 23, Arslan, S. *et al.*, *Sequencing by avidity enables high accuracy with low reagent consumption*, Nature Biotechnology 42:132–38, at 134 (2023) (the "Element 2023 Publication") (emphases added).) The "two excitation lines" described in the publication are emitted by excitation light sources, the cameras are imaging detectors, and the multiple tube lenses and the objective lens are included in an optical train. The AVITI24 contains similar components. It "contains a Class 4 laser," which is an excitation light source. (Ex. 22, AVITI24 System User Guide at 59.) During sequencing on the AVITI24, "a camera and four tube lenses above the nest image the flow cell in four channels." (*Id.* at 8.) The camera is an imaging device, and the four tube lenses are included in an optical train because they are a collection of components to guide light.

81. That the AVITI Systems include an optical system is further supported by the disclosures of Element's patents and abandoned patent applications that purportedly cover the AVITI Systems.[2] These include U.S. Patent No. 11,459,608 (the "'608 Patent"). (Ex. 25, '608 Patent.) The '608 Patent discloses an excitation light source (Excitation Beams 1 and 2 in the image below), an imaging detector (Imaging Sensors 1–4 in the image below) and an optical train (the tube lens in the image below, which are components of an optical train because they direct the excitation light sources).

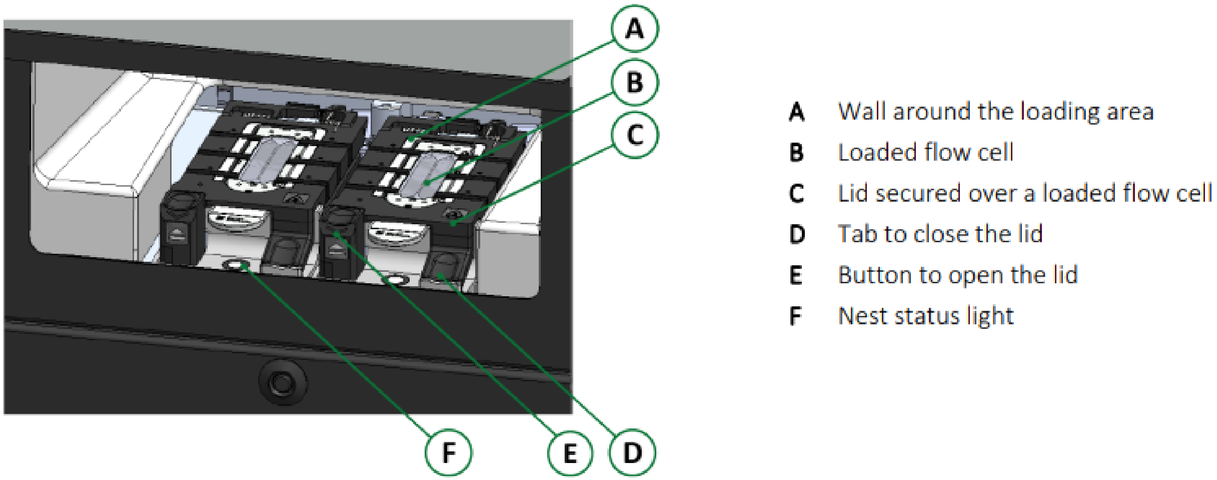
[2] *See* Ex. 24, Element AVITI System Workflow Guide at 2.


Excitation Beam 2
Autofocus Laser Beam
Excitation Beam 1
Flow cell
objective
Tube lens
Imaging Sensor 4
Imaging Sensor 3
Autofocus Sensor
Imaging Sensor 2
Imaging Sensor 1

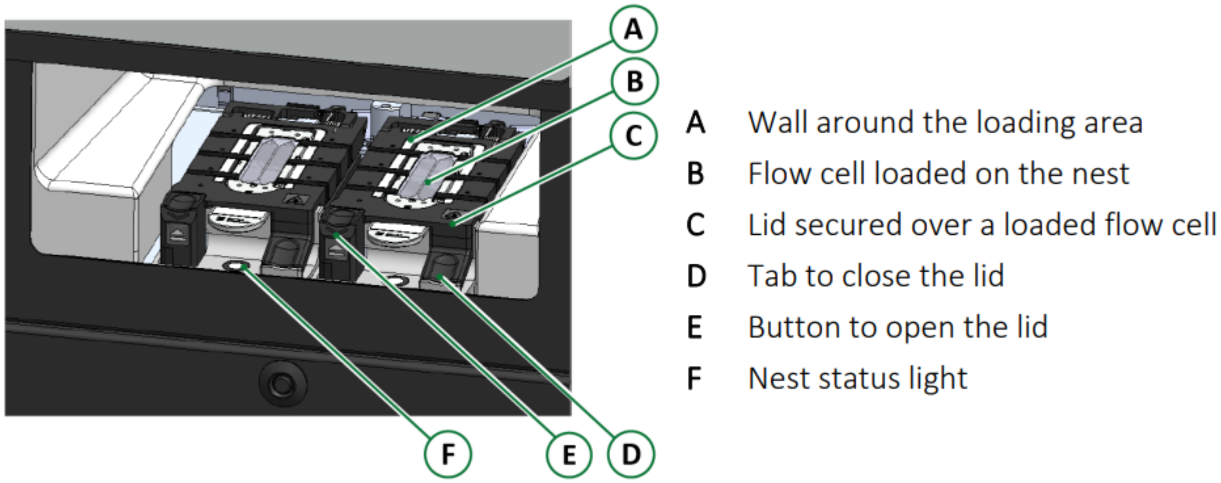
(Ex. 25, '608 Patent, Fig. 18.)

82. "a device holder to orient a fluidic device for imaging by the optical system, the fluidic device comprising a flow cell." Element's AVITI Systems include a device holder as recited in Claim 1 of the '241 Patent. Specifically, the AVITI Systems contain two nests within a nest bay; as discussed below, each nest and lid is a device holder. The AVITI System Workflow Guide states that "[t]he nest bay includes two nests, one for each side. ***Each nest holds one flow cell secured with a lid***." (Ex. 24, AVITI System Workflow Guide at 13 (emphasis added); *see also* Ex. 22, AVITI24 System User Guide at 8 ("The nest bay includes two nests, one for each side, and ***each nest holds one flow cell***." (emphasis added)).) The nest and lid (the device holder) guide the placement of the flow cell and its plastic cartridge (together, the fluidic device). That is, the device holder orients a fluidic device for imaging by the optical system. The nests

with loaded flow cells in plastic cartridges (labeled "B")—the fluidic devices—are shown in these images from Element's product guides:


A
B
C
F
E
D
A Wall around the loading area
B Loaded flow cell
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

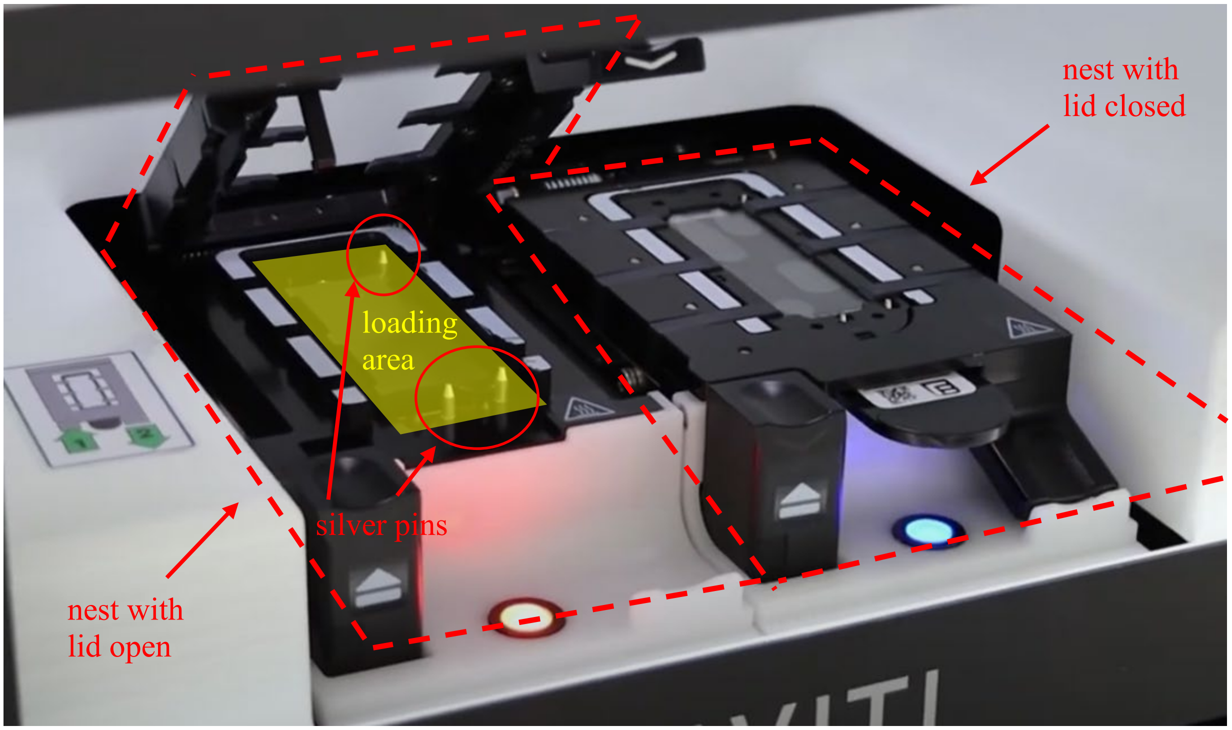
(Ex. 24, AVITI System Workflow Guide at 13.)


A
B
C
F
E
D
A Wall around the loading area
B Flow cell loaded on the nest
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

(Ex. 22, AVITI24 System User Guide at 8.)

83. "a support structure including a loading region to receive the fluidic device, the loading region including a base surface to have the fluidic device positioned thereon." Element's AVITI Systems have a support structure that includes a loading region as recited in Claim 1 of the '241 Patent. The nest (the support structure) has a loading area (a loading region) that includes three

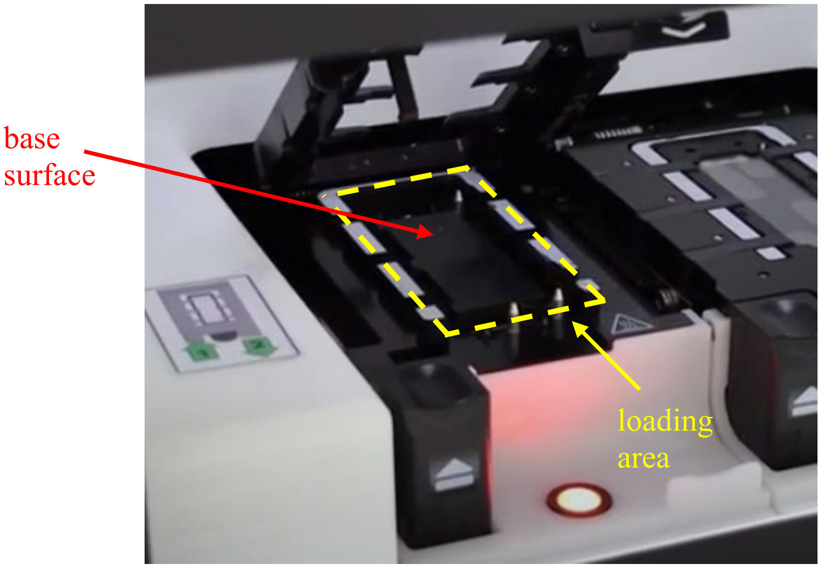
silver pins. (*See* Ex. 24, AVITI System Workflow Guide at 13 ("Three silver pins fit into three corresponding holes on the flow cell cartridge, ensuring proper alignment and seating."); *id.* at 52 (directing the user to load the flow cell and plastic cartridge into the nest by "plac[ing] the flow cell over the three registration pins on the nest"); *see also* Ex. 22, AVITI24 System User Guide at 8 ("To ensure proper alignment, three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge.").) The nest (the support structure) and its loading area (the loading region) are shown in the diagram below.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

84. The loading region includes a base surface to have the fluidic device positioned thereon. The base surface is shown in the image below. When

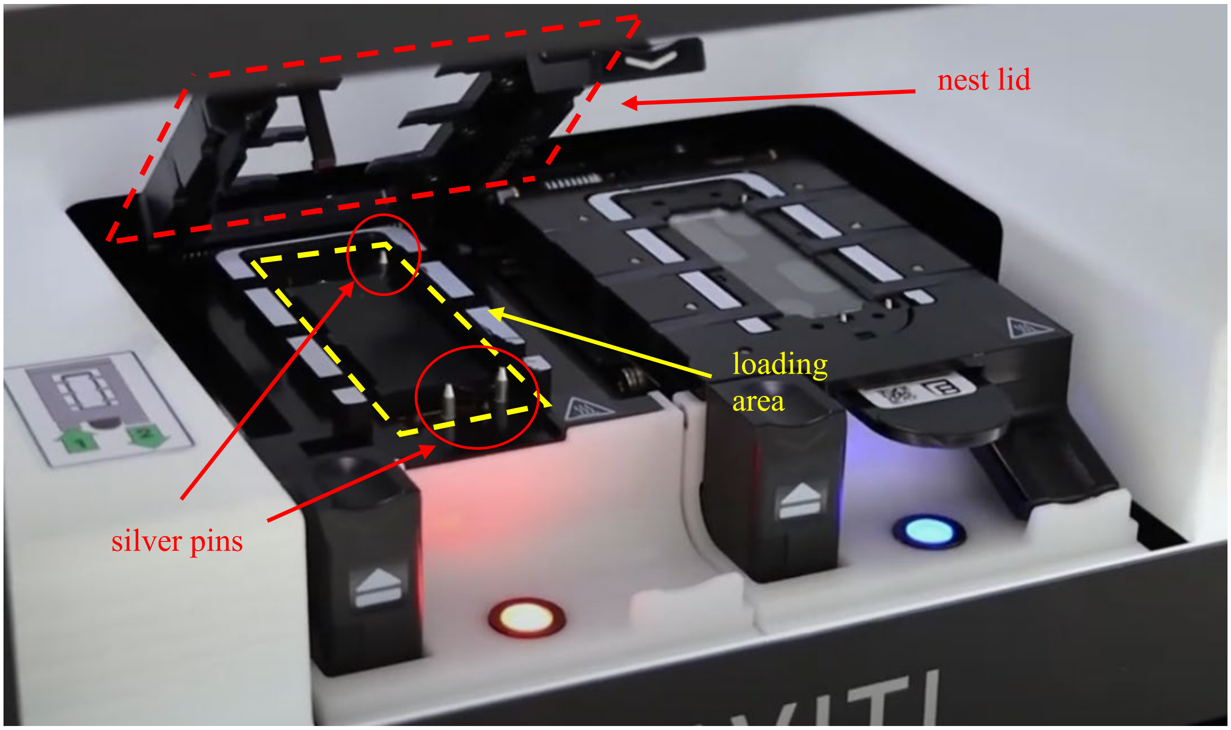
the flow cell and plastic cartridge (the fluidic device) are loaded into the nest, the three silver pins extend through apertures in the plastic cartridge for alignment on top of the base surface.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

85. "a rotatable cover that is coupled to the support structure and moveable about an axis between an open position and a closed position, the cover movable to the open position to permit the fluidic device to be inserted into and removed from the loading region and movable to the closed position to secure the fluidic device within the loading region for imaging." Element's AVITI Systems have a rotatable cover as recited in Claim 1 of the '241 Patent. "Each nest holds one flow cell secured with a lid. A button unlatches and opens the lid to a 40° angle. A tab closes the lid and secures the flow cell." (Ex. 24, AVITI System Workflow Guide at 13; *see also* Ex. 22, AVITI24 System User Guide at 8 ("A

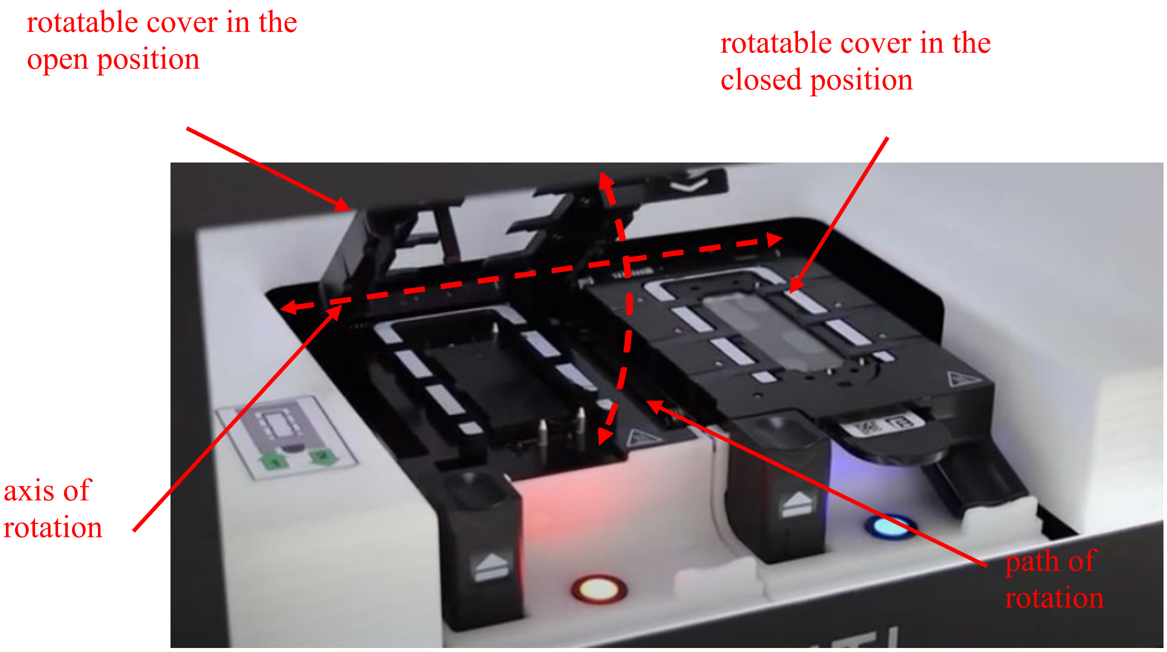
hinged flow cell lid secures the flow cell in place. A button on each nest unlatches and opens the hinged lid to a 40° angle.”).) The nest lid, which Element typically calls a “flow cell lid,” is a rotatable cover. (Ex. 9, AVITI System User Guide at 8 (“A hinged flow cell lid secures the flow cell in place.”); Ex. 22, AVITI24 System User Guide at 8 (same).) It is coupled to the nest (the support structure). The image below depicts the nest lid (the rotatable cover) coupled to the nest (the support structure), which includes the loading area and the three silver pins.



(Ex. 26, “Element AVITI™ System - Instrument Demonstration,” https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

86. The nest lid (the rotatable cover) moves about an axis between an open position and a closed position. When the nest lid is in the open position, the fluidic device—the flow cell and plastic cartridge—may be inserted into and

removed from the loading region. The nest lid (the rotatable cover) may then be moved to the closed position. When the rotatable cover is closed, the fluidic device is secured within the loading area for imaging. (Ex. 9, AVITI System User Guide at 8 ("A hinged flow cell lid secures the flow cell in place. . . . During a run, a camera and four tube lenses above the nest image the flow cell in four channels."); Ex. 22, AVITI24 System User Guide at 8 (same).) The cover in its open and closed positions and the axis of rotation of the cover are shown in the image below.

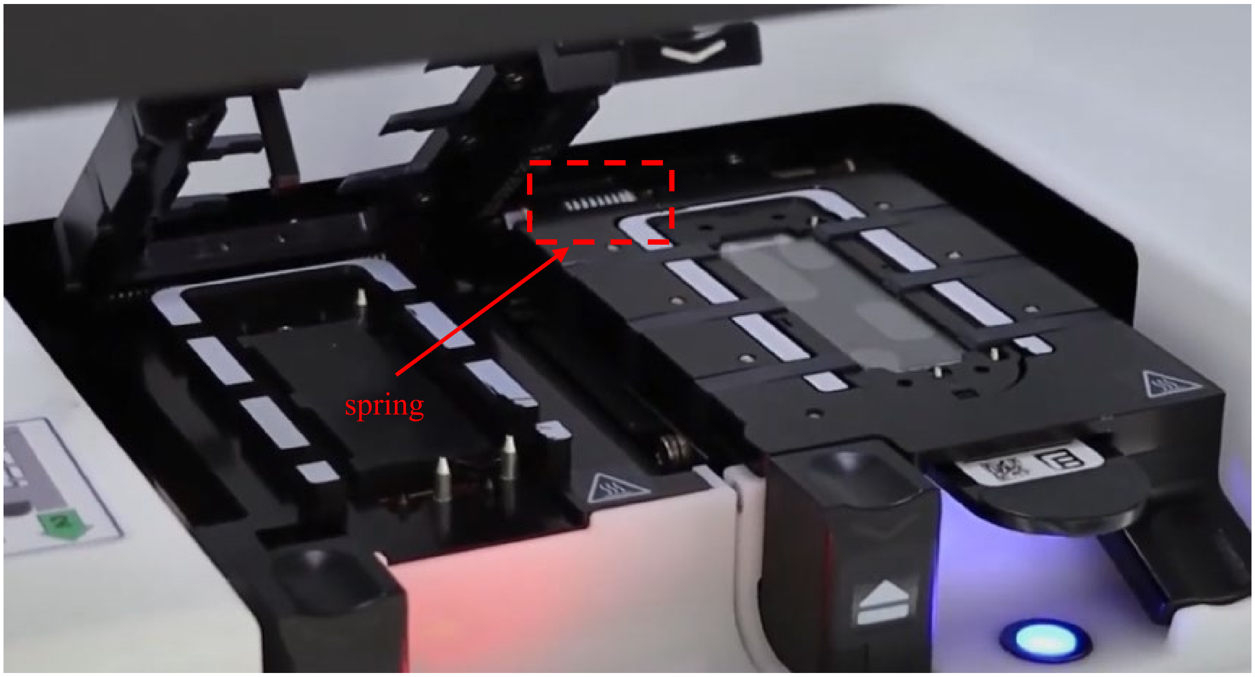

rotatable cover in the open position
rotatable cover in the closed position
axis of rotation
path of rotation

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

87. "wherein the cover is biased toward the open position."

Element's AVITI Systems' cover is biased toward the open position as recited in

Claim 1 of the '241 Patent. The AVITI System Workflow Guide provides that "[a] button unlatches and opens the lid to a 40° angle. A tab closes the lid and secures the flow cell." (Ex. 24, AVITI System Workflow Guide at 13; *see also* Ex. 22, AVITI24 System User Guide at 8 ("A button on each nest unlatches and opens the hinged lid to a 40° angle."); Ex. 24, AVITI System Workflow Guide at 52 ("Press the button to the left of the nest to open the lid. . . . Lower the tab on the right side of the lid until the lid snaps into place.").) Because the nest lid (the rotatable cover) automatically opens to the 40° angle when it is not fully latched in the closed position, the nest lid is "biased" toward the open position. As shown in the images below, a spring in the rotatable cover biases the cover toward the open position.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

88. "a latch to releasably hold the cover in the closed position."

Element's AVITI Systems include a latch as recited in Claim 1 of the '241 Patent. "A button unlatches and opens the lid to a 40° angle. A tab closes the lid and secures the flow cell." (Ex. 24, AVITI System Workflow Guide at 13; *see also id.* at 52 ("Press the button to the left of the nest to open the lid. . . . Lower the tab on the right side of the lid until the lid snaps into place."); Ex. 22, AVITI24 System User Guide at 8 ("A button on each nest unlatches and opens the hinged lid to a 40° angle.").) The figure below shows the latch releasably holding the nest lid (rotatable cover) in the closed position.

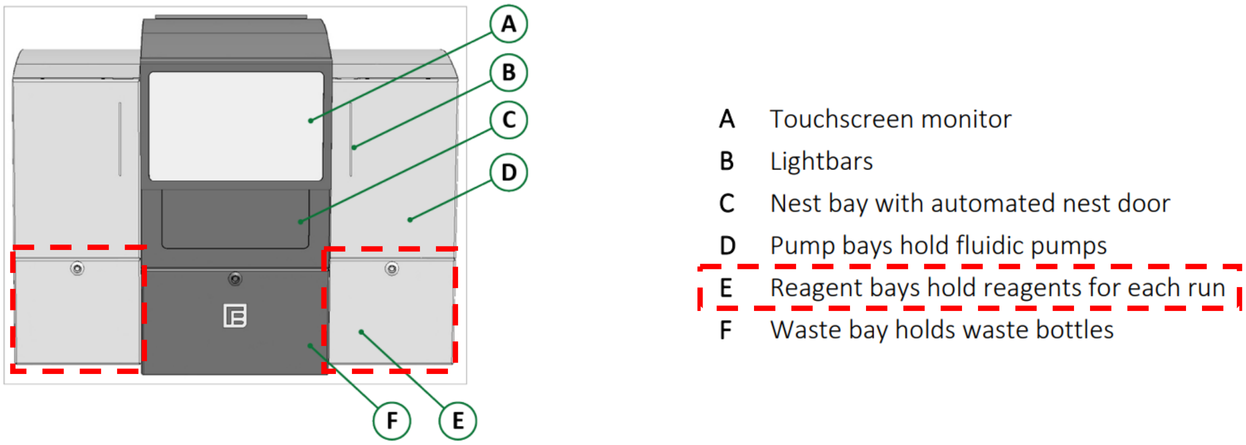
cover latched in the closed position

latch

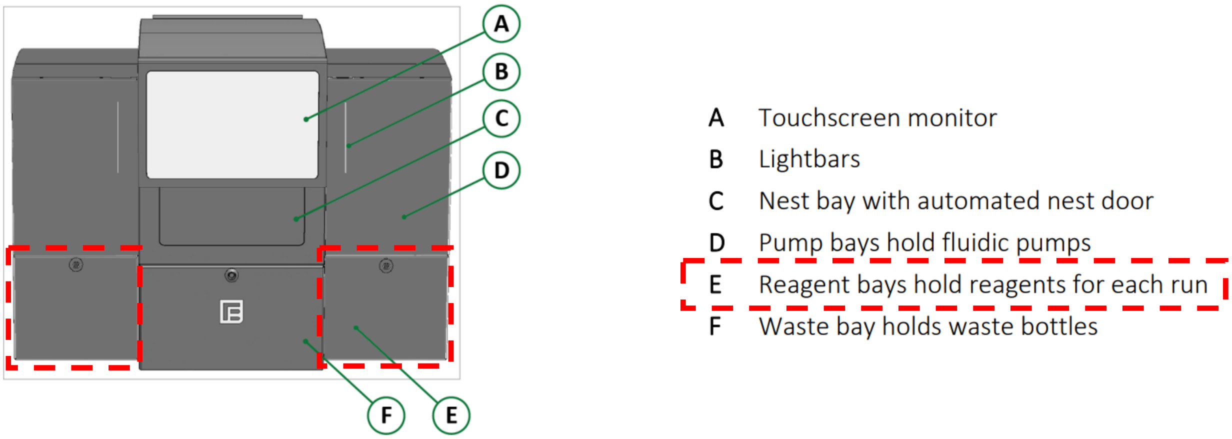
(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

89. "a fluid storage system comprising." Element's AVITI Systems include a fluid storage system, as recited in Claim 1 of the '241 Patent. The AVITI Systems store and distribute fluids (reagents and washes) in bottles and cartridges. (*See* Ex. 9, AVITI System User Guide at 9 ("Each pump bay contains two pumps that control the flow of liquid. . . . Each reagent bay holds a buffer bottle and cartridge basket that contains a cartridge or a wash tray, depending on whether the system is sequencing or washing. . . . When priming starts, sippers descend into the bay, pierce the foil seals covering the cartridge wells, and aspirate reagents from the bottom of each well."); Ex. 22, AVITI24 System User Guide at 9 (same).)

90. "an enclosure having a cavity." Element's AVITI Systems have an enclosure as recited in Claim 1 of the '241 Patent. The AVITI Systems have an enclosure on each side, which encompasses at least the reagent bay. (Ex. 9, AVITI System User Guide at 7 ("Side A and B each include a dedicated pump bay and reagent bay enclosed with bay doors."); Ex. 22, AVITI24 System User Guide at 7 (same).) The reagent bay on each side is denoted using the dashed red lines in the images below.

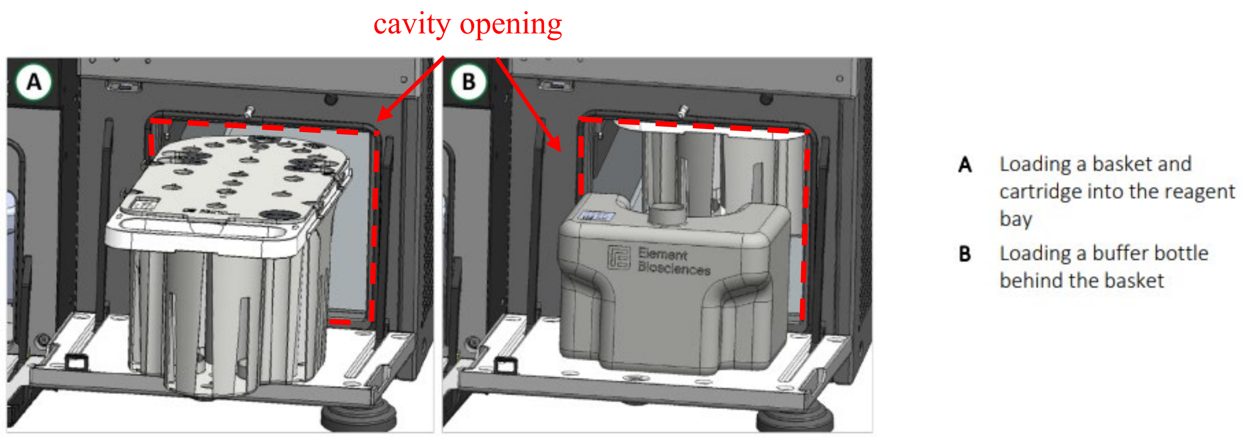

A
B
C
D
E
F
A Touchscreen monitor
B Lightbars
C Nest bay with automated nest door
D Pump bays hold fluidic pumps
E Reagent bays hold reagents for each run
F Waste bay holds waste bottles

(Ex. 9, AVITI System User Guide at 7 (green annotation in original, red annotations added).)


A
B
C
D
E
F
A Touchscreen monitor
B Lightbars
C Nest bay with automated nest door
D Pump bays hold fluidic pumps
E Reagent bays hold reagents for each run
F Waste bay holds waste bottles

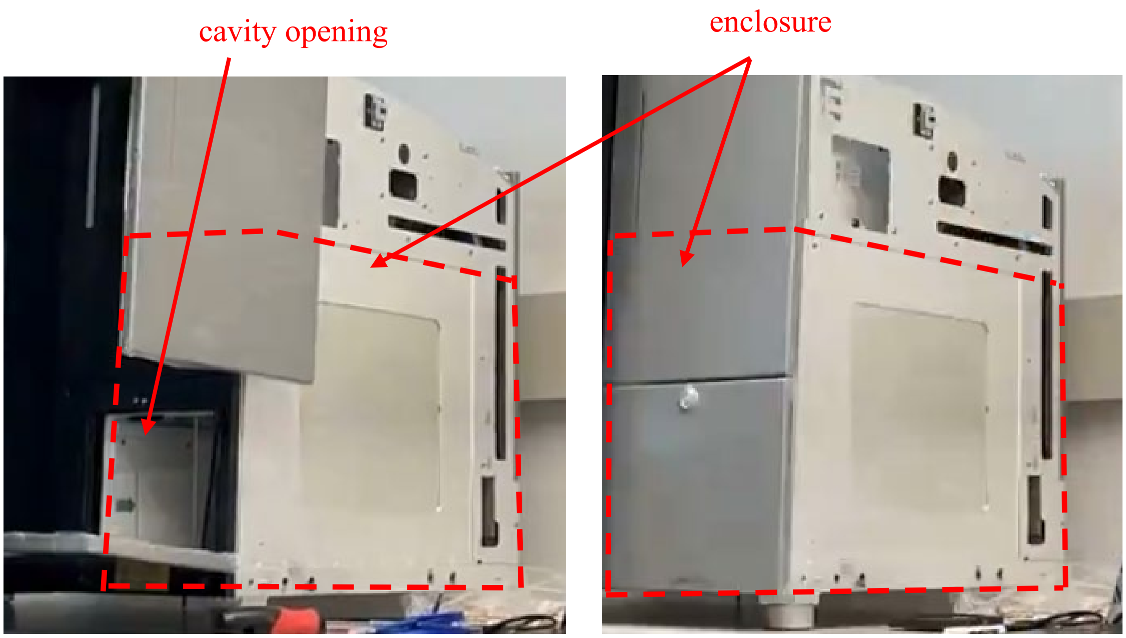
(Ex. 22, AVITI24 System User Guide at 7 (green annotation in original, red annotations added).)

91. "Each reagent bay holds a buffer bottle and cartridge basket that contains a cartridge or a wash tray, depending on whether the system is sequencing or washing." (Ex. 9, AVITI System User Guide at 9; Ex. 22, AVITI24 System User Guide at 9 (same).) The enclosure (which includes at least the reagent bay) makes up a single cavity. An opening to this cavity is shown in the image below.

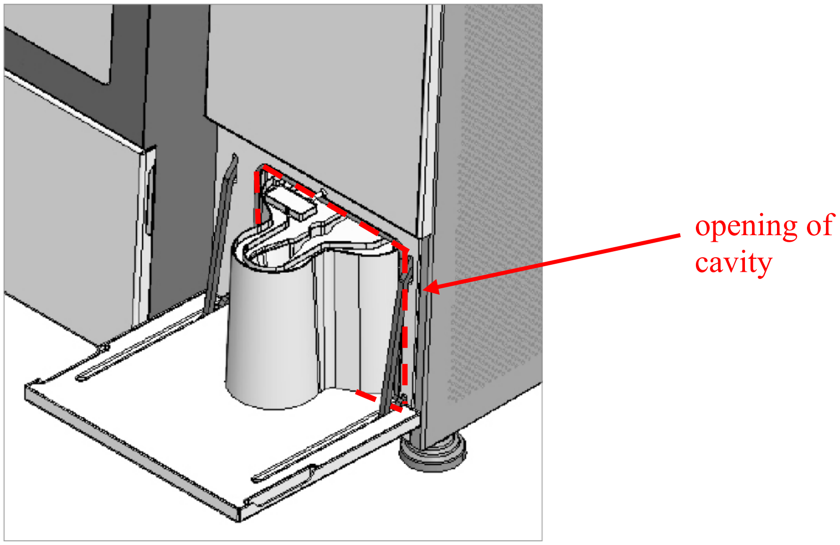

cavity opening
A
B
Element Biosciences
A Loading a basket and cartridge into the reagent bay
B Loading a buffer bottle behind the basket

(Ex. 24, AVITI System Workflow Guide at 15 (annotated).)

92. An unboxing video of the AVITI instrument shows the enclosure and the cavity:

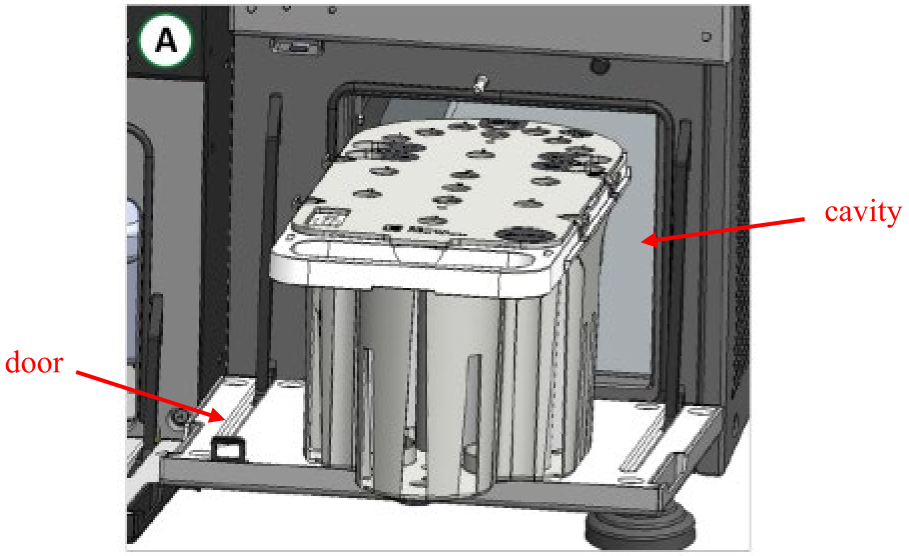

cavity opening
enclosure

(Ex. 27, "behind-the-scenes moment of unboxing and installing @ElemBio AVITI," https://x.com/TrendBio/status/1772752893663224019 at 1:00, 1:03 (Mar. 26, 2024) (annotated).)

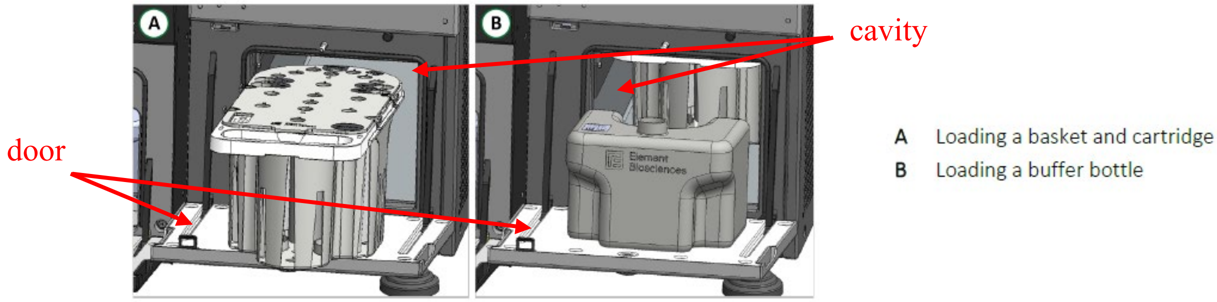


(Ex. 22, AVITI24 System User Guide at 31 (annotated).)

93. "a door openable to provide access to the cavity." Element's AVITI Systems have the door as recited in Claim 1 of the '241 Patent. The reagent bay doors are doors that are openable to provide access to the cavity. The AVITI System Workflow Guide directs the user to "[k]eep the ***reagent bay doors*** closed to maintain refrigeration, which chills reagents." (Ex. 24, AVITI System Workflow Guide at 14 (emphasis added); *see also id*. at 66 ("When prompted, open ***the reagent bay door***." (emphasis added)).) The AVITI24 System User Guide similarly directs the user to "[k]eep the ***reagent bay doors*** closed to maintain the refrigeration, which chills reagents." (Ex. 22, AVITI24 System User Guide at 9 (emphasis added).) The door, in the opened configuration, is shown in the images below. The door can be closed when the cartridge or bottle is pushed into the cavity.



(Ex. 24, AVITI System Workflow Guide at 15 (annotated).)



(Ex. 22, AVITI24 System User Guide at 9 (annotated).)

94. "a transport platform holding an array of sipper tubes, each sipper tube of the array of sipper tubes includes a distal portion positioned to be inserted into a component well of a reaction component tray within the cavity." Element's AVITI Systems include a transport platform holding an array of sipper tubes as recited in Claim 1 of the '241 Patent. The system has an array of sipper tubes. The AVITI's sipper tubes are positioned to be inserted into a component well of a reaction component tray within the cavity: "When priming starts, ***sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing]***

cartridge wells, and aspirate reagents from the bottom of each well. The sippers continue to aspirate reagents throughout the run. Functioning similarly for a wash, the sippers aspirate wash solution instead of reagents." (Ex. 24, AVITI System Workflow Guide at 14 (emphasis added); *see also* Ex. 22, AVITI24 System User Guide at 9 (describing a similar set of sipper tubes which also "descend into the [reagent] bay").)

95. To move up and down in unison, the sipper tubes in the AVITI Systems are attached to a transport platform. The transport platform moves up and down, causing the sipper tubes to either descend into the reagent bay where the sequencing cartridge (the reaction component tray) is received or ascend toward a withdrawn position above where the sequencing cartridge is received. Because the sippers descend into the reagent bay, each sipper tube of the array of sipper tubes includes a distal portion (the downward end that aspirates the fluid) positioned to be inserted into the sequencing cartridge wells (the component well) of a sequencing cartridge (the reaction component tray) within the cavity.

96. "a drive motor operatively coupled to the transport platform, the transport platform moveable by the drive motor to position the array of sipper tubes at least partially within the cavity." Element's AVITI Systems include a drive motor as recited in Claim 1 of the '241 Patent. The AVITI Systems include an array of sipper tubes, which aspirate (remove) the reagents (fluids) from a

sequencing cartridge in the reagent bay (part of the cavity). (Ex. 24, AVITI System Workflow Guide at 14 ("When priming starts, sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well."); *see also* Ex. 22, AVITI24 System User Guide at 9 (same).) For the sippers to descend into the reagent bay in the AVITI Systems, a drive motor is operatively coupled to the transport platform holding the array of sipper tubes. Also, for the tubes to "pierce the foil seals covering the sequencing cartridge wells, and aspirate reagents from the bottom of each well" in the AVITI Systems, the drive motor moves the transport platform to position the sipper tubes in the sequencing cartridge wells, which are located in the fluid storage system cavity. Thus, in the AVITI Systems, the drive motor moves the array of sipper tubes at least partially within the cavity.

97. "a casing enclosing the optical system, the device holder, and the fluid storage system therein." Element's AVITI Systems have a casing as recited in Claim 1 of the '241 Patent. "Exterior shells enclose the instrument to maintain internal temperatures, exclude dust and other external elements, and protect operators from exposure to lasers, mechanical moving parts, and other internal hazards." (Ex. 24, AVITI System Workflow Guide at 12.) The below images show the casing that encloses the optical system (*see supra* ¶¶ 80–81), the fluidic device holder (*see supra* ¶ 82) and the fluid storage system (*see supra* ¶ 89):

A
B
C
D
E
F
G
H
AVITI

Parts

A Touchscreen user interface for run setup

B Fluidics pump bay side A

C Fluidics pump bay side B

D Flow cell nest bay

E Ventilated housing

F Two waste bottles, one per flow cell

G Sequencing reagent cartridge side A

H Sequencing reagent cartridge side B

(Ex. 28, "AVITI – Specifications," (June 6, 2023, 10:41 PM), https://www.elementbiosciences.com/products/aviti/specs [https://web.archive.org/web/20230606224136/https://www.elementbiosciences.com/products/aviti/specs].)

AVITI 24
AVITI

(Ex. 29, "AVITI24 System and Specifications," https://www.elementbiosciences.com/products/aviti24/platform (showing the casing for the AVITI24).)

98. The exterior shells are a casing enclosing the optical system, the device holder and the fluid storage system therein. (Ex. 24, AVITI System Workflow Guide at 11 ("***Internally***, a ***camera and four tube lenses*** image the flow cell in four channels." (emphasis added)); Ex. 22, AVITI24 System User Guide at 6 ("Exterior shells enclose the instrument to protect the operator from ***laser light*** exposure and mechanical parts." (emphasis added)); Ex. 24, AVITI System Workflow Guide at 13 ("The nest bay includes two ***nests***, one for each side." (emphasis added)); Ex. 22, AVITI24 System User Guide at 8 (same); Ex. 9, AVITI System User Guide at 7 ("Side A and B each include a dedicated ***pump bay and reagent bay*** enclosed with bay doors." (emphasis added)); Ex. 22, AVITI24 System User Guide at 7 (same).)

99. As shown above, the AVITI Systems satisfy each and every limitation of Claim 1 of the '241 Patent. The AVITI Systems also satisfy each and every limitation of at least Claims 2–3, 7–12, 14, 15–16, 17 and 18–20.

100. In violation of 35 U.S.C. § 271(a), Element has infringed the '241 Patent by making, using, offering to sell and selling the AVITI Systems.

101. In addition to directly infringing, in violation of 35 U.S.C. § 271(b), Element has induced and continues to induce its customers to directly

infringe the ’241 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on Element’s website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element’s customers and prospective customers and/or providing technical support or other services for the products to Element’s customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the “device holder to orient a fluidic device,” and loading reagents and fluids into the reagent bay (Ex. 24, AVITI System Workflow Guide at 51–52; Ex. 22, AVITI24 System User Guide at 30–32), thereby making use of the “fluid storage system.” Element knows that when Element’s customers use the AVITI Systems as directed by Element, Element’s customers are directly infringing the ’241 Patent.

102. Element has been on notice of the infringement alleged in this Count since on or around the issuance of the ’241 Patent on November 26, 2024. Alternatively, Element has been on notice of the ’241 Patent at least since May 15, 2025, when Illumina filed and served on Element a complaint alleging that

Element infringes the ’241 Patent. Element has committed acts of infringement willfully and intentionally after notice of infringement.

103. Element purchased a MiSeq instrument from Illumina in February 2019. This instrument included a label noting that the patents associated with it can be accessed at www.illumina.com/patents. Element used the MiSeq instrument in its development of the AVITI Systems.

104. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT II: INFRINGEMENT OF THE ’781 PATENT

105. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

106. Element has infringed at least Claims 30, 31, 38–39 and 42–43 of the ’781 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell and selling within the United States the inventions claimed in the ’781 Patent.

107. Independent Claim 30 of the ’781 Patent recites:

> A fluidic device holder configured to orient a fluidic device with respect to mutually perpendicular X, Y, and Z-axes, the device holder comprising:
>
> a support structure configured to receive a fluidic device, the support structure including a base surface that faces in a direction along the Z-axis and is configured to have the fluidic device positioned thereon;
>
> a plurality of reference surfaces facing in respective directions along an XY-plane;

> an alignment assembly comprising an actuator and a movable locator arm that is operatively coupled to the actuator, the locator arm having an engagement end, the actuator moving the locator arm between retracted and biased positions to move the engagement end away from and toward the reference surfaces, wherein the engagement end presses, in a direction along the XY plane, the fluidic device against the reference surfaces when the locator arm is in the biased position such that the fluidic device is held between the engagement end and the reference surfaces in a fixed position with respect to the support structure, wherein the locator arm includes a finger, the finger including the engagement end.

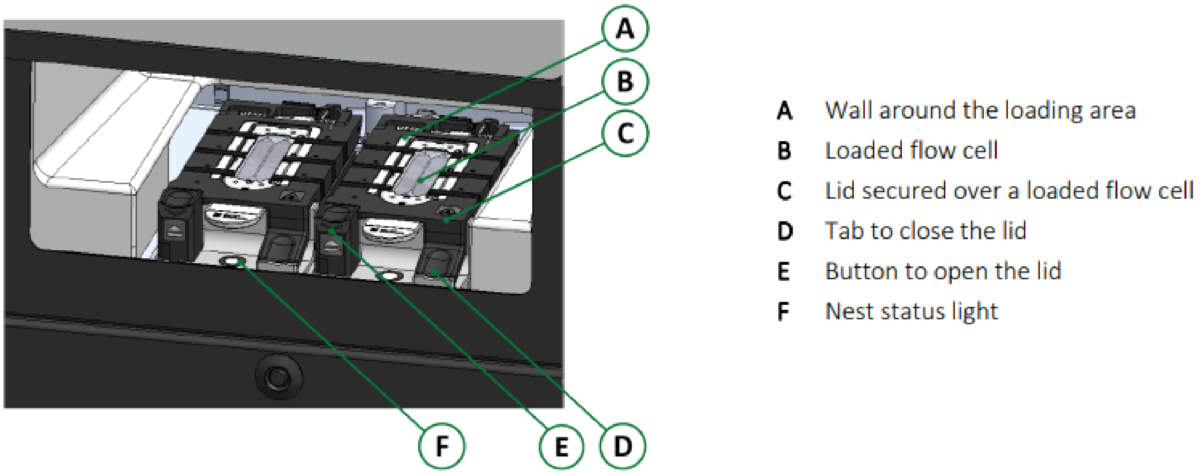
(Ex. 3, '781 Patent at 55:19–40.)

108. "A fluidic device holder configured to orient a fluidic device with respect to mutually perpendicular X, Y, and Z-axes." Element's AVITI Systems include the fluidic device holder recited in Claim 30 of the '781 Patent. Specifically, the AVITI Systems contain two nests within a nest bay. (Ex. 24, AVITI System Workflow Guide at 13 ("The nest bay includes two nests, one for each side."); Ex. 22, AVITI24 System User Guide at 8 (same).) Each nest has a nest lid (which Element calls a flow cell lid); as discussed below, together each nest and nest lid is a fluidic device holder. (Ex. 9, AVITI System User Guide at 8 ("A hinged flow cell lid secures the flow cell in place."); Ex. 22, AVITI24 System User Guide at 8 (same).)

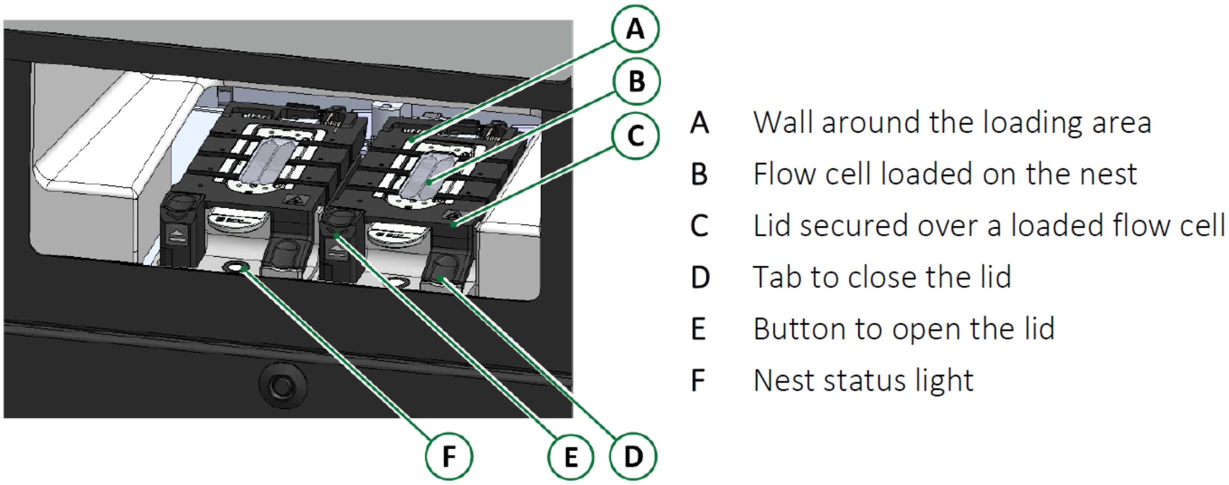
109. The '781 Patent states that "a 'fluidic device' is an apparatus that includes one or more flow channels that direct fluid in a predetermined manner to conduct desired reactions." (Ex. 3, '781 Patent at 12:13–15.) Each flow cell

and plastic cartridge of the AVITI Systems is a fluidic device. (Ex. 9, AVITI System User Guide at 13 ("The flow cell is a two-lane glass substrate encased in a plastic cartridge. . . . Library and reagents enter the flow cell through inlet ports and exit as waste through outlet ports."); Ex. 22, AVITI24 System User Guide at 13 (same).) Each nest and nest lid is a fluidic device holder that holds a flow cell and plastic cartridge (the fluidic device). (Ex. 24, AVITI System Workflow Guide at 13 ("Each nest holds one flow cell secured with a lid."); *see also* Ex. 22, AVITI24 System User Guide at 8 ("The nest bay includes two nests, one for each side, and each nest holds one flow cell.").)

110. The two nests and their nest lids (the fluidic device holders), each of which can receive a flow cell and plastic cartridge (the fluidic device), are shown below in diagrams from Element's user guides for the accused AVITI Systems.

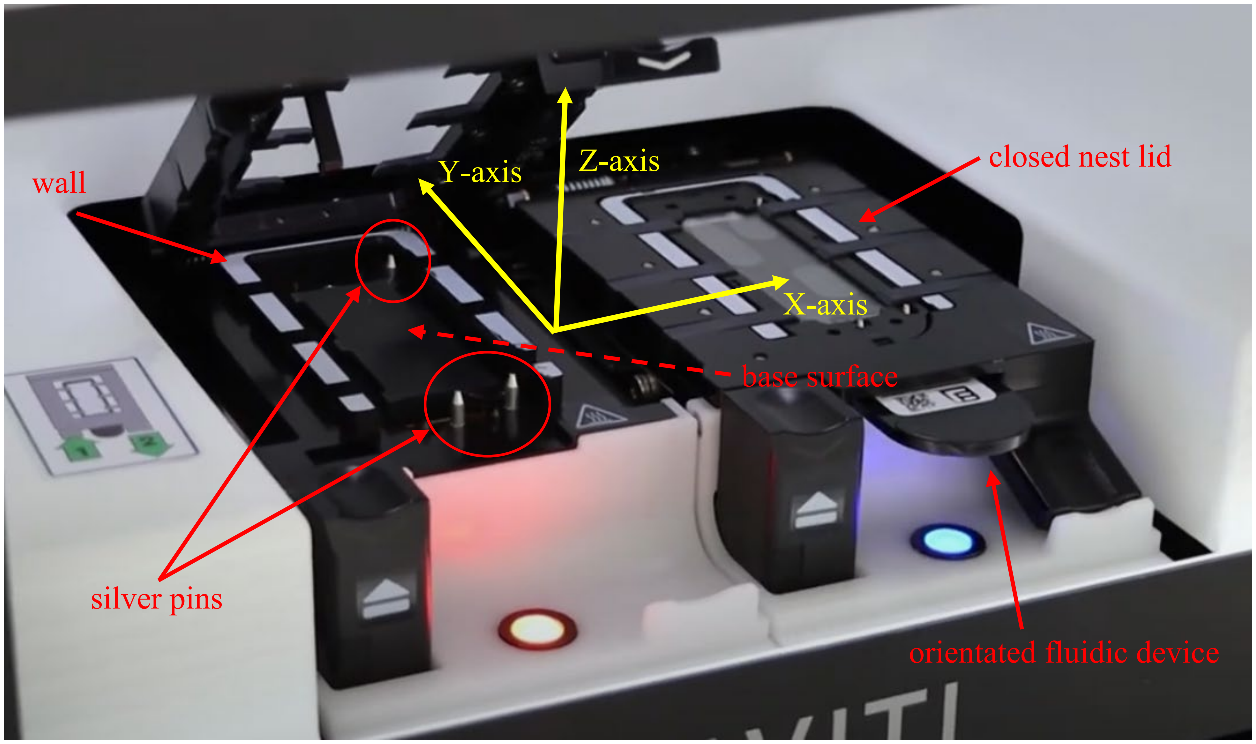

A
B
C
D
E
F
A Wall around the loading area
B Loaded flow cell
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

(Ex. 24, AVITI System Workflow Guide at 13.)


A
B
C
D
E
F
A Wall around the loading area
B Flow cell loaded on the nest
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

(Ex. 22, AVITI24 System User Guide at 8.)

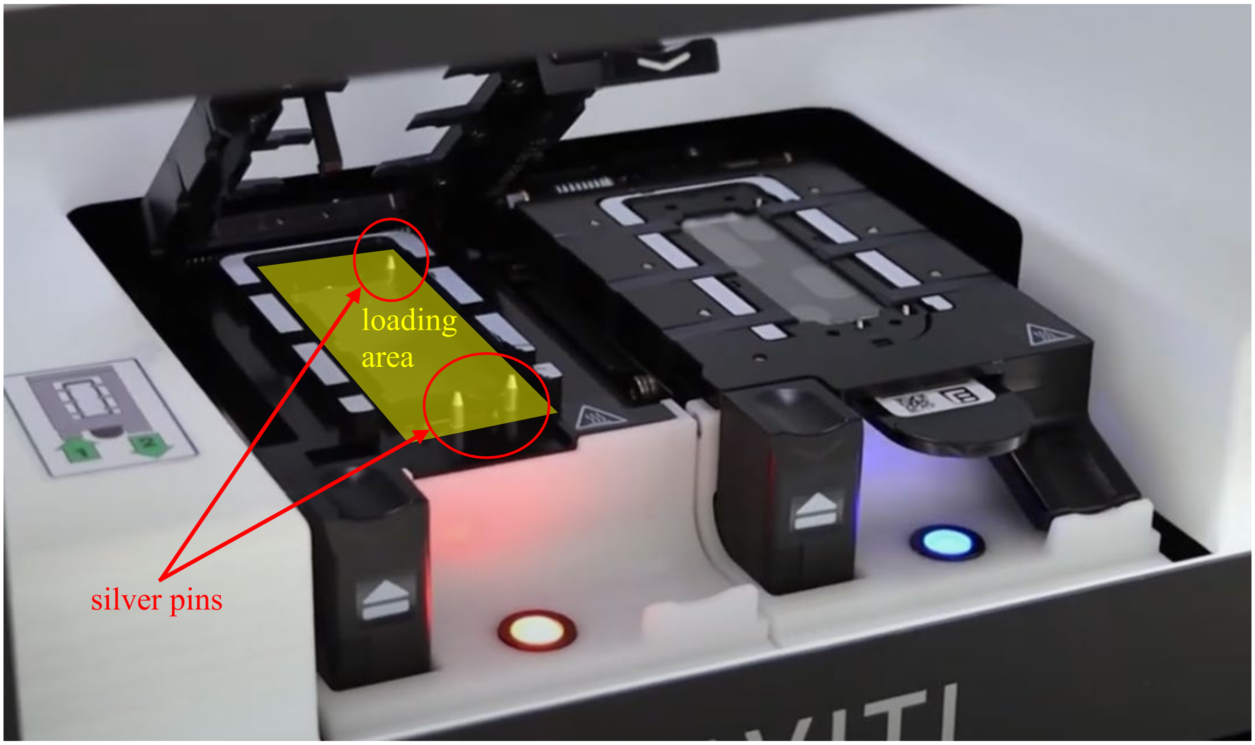
111. The nest and nest lid (the fluidic device holder) are configured to orient the fluidic device along the X, Y and Z-axes. Specifically, the AVITI System Workflow Guide states that the nest has "[a] wall [that] encircles the loading area. Three silver pins fit into three corresponding holes on the flow cell cartridge, ***ensuring proper alignment and seating***." (Ex. 24, AVITI System Workflow Guide at 13 (emphasis added); *see also* Ex. 22, AVITI24 System User Guide at 8 ("A hinged flow cell lid secures the flow cell in place. . . . ***To ensure proper alignment***, three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge." (emphasis added)).) In addition, the base surface and the lid of the nest (in a closed position) are configured to orient the fluidic device in the Z-direction. The wall, three silver pins, base surface and lid orient the fluidic device with respect to mutually perpendicular X, Y and Z-axes, as shown in the image below.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

112. "a support structure configured to receive a fluidic device."

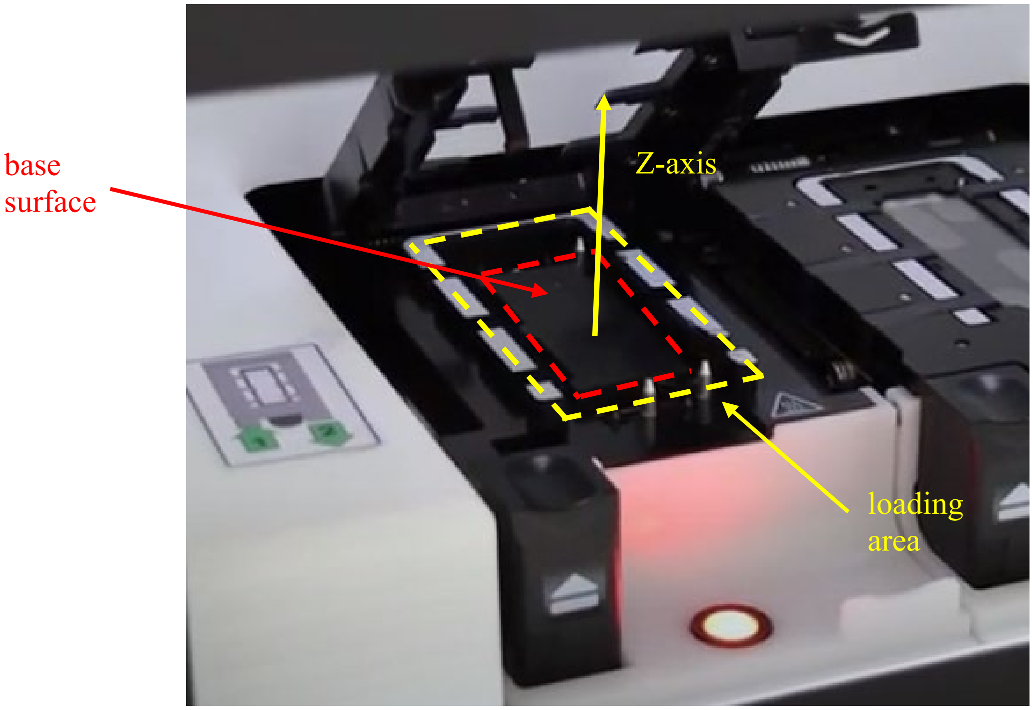
Element's AVITI Systems have a support structure as recited in Claim 30 of the '781 Patent. Specifically, the nest (the support structure) includes the loading area and three silver pins (show in the image below). The nest (the support structure) is configured to receive the flow cell and plastic cartridge (the fluidic device). (*See* Ex. 24, AVITI System Workflow Guide at 13 ("Three silver pins fit into three corresponding holes on the flow cell cartridge, ensuring proper alignment and seating."); *id.* at 52 (directing the user to load the flow cell into the nest by "plac[ing] the flow cell over the three registration pins on the nest"); Ex. 22, AVITI24 System User Guide at 8 ("To ensure proper alignment, three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge.").)



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

113. "the support structure including a base surface that faces in a direction along the Z-axis and is configured to have the fluidic device positioned thereon." Element's AVITI Systems have a support structure including a base surface as recited in Claim 30 of the '781 Patent. The loading area of the nest (the support structure) includes a surface (the base surface) as shown in the image below. The surface faces in a direction along the Z-axis, as shown in the image. The surface is configured to have the fluidic device positioned thereon: when the flow cell and the plastic cartridge (the fluidic device) are loaded into the nest, the

three silver pins extend through apertures in the frame of the plastic cartridge for alignment on top of the base surface.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

114. "a plurality of reference surfaces facing in respective directions along an XY-plane." The '781 Patent discloses that, in one embodiment, the "reference surfaces" are the surfaces facing in the XY-plane of three cylindrical protrusions from the loading region, as depicted in Figure 18, which is replicated below. In this embodiment, "[t]he loading region **422** may be partially defined by the base surface 430 and the reference surfaces of the alignment members **431-433**." (Ex. 3, '781 Patent at 30:33–36.) In the embodiment depicted below, the alignment members are pins protruding from the loading region.

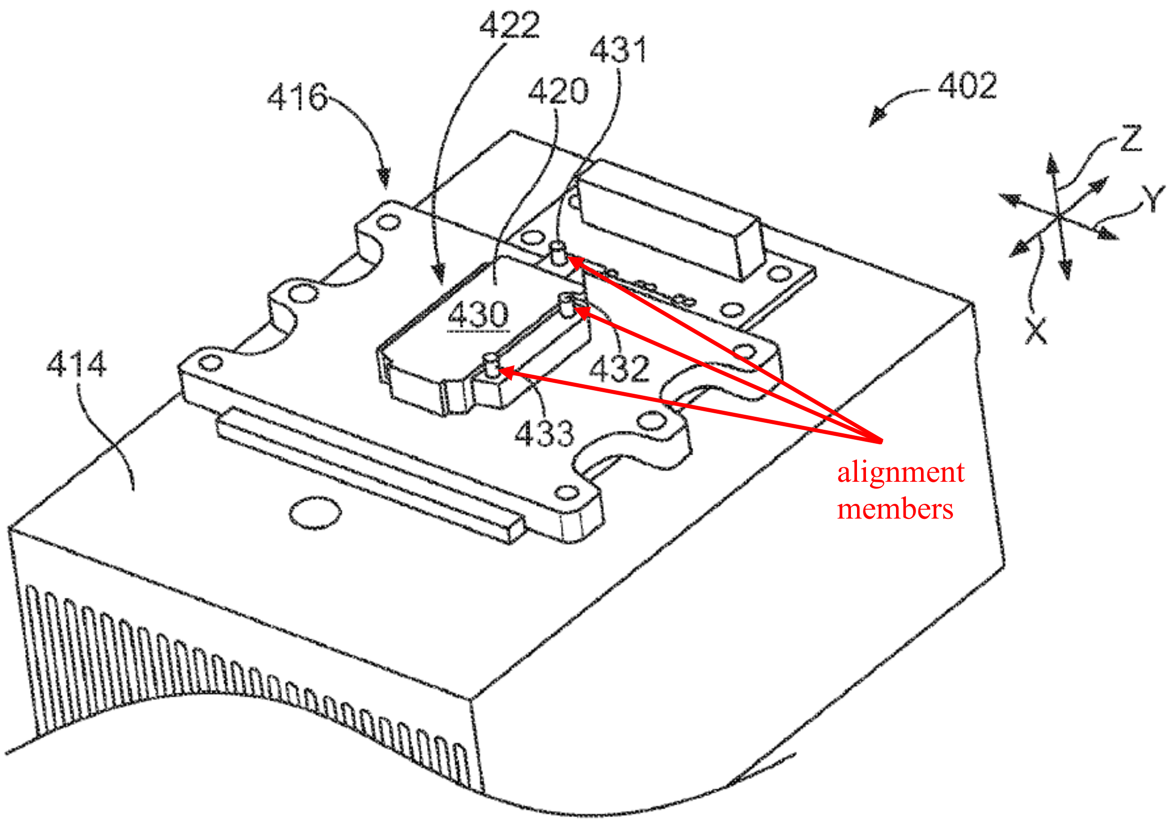


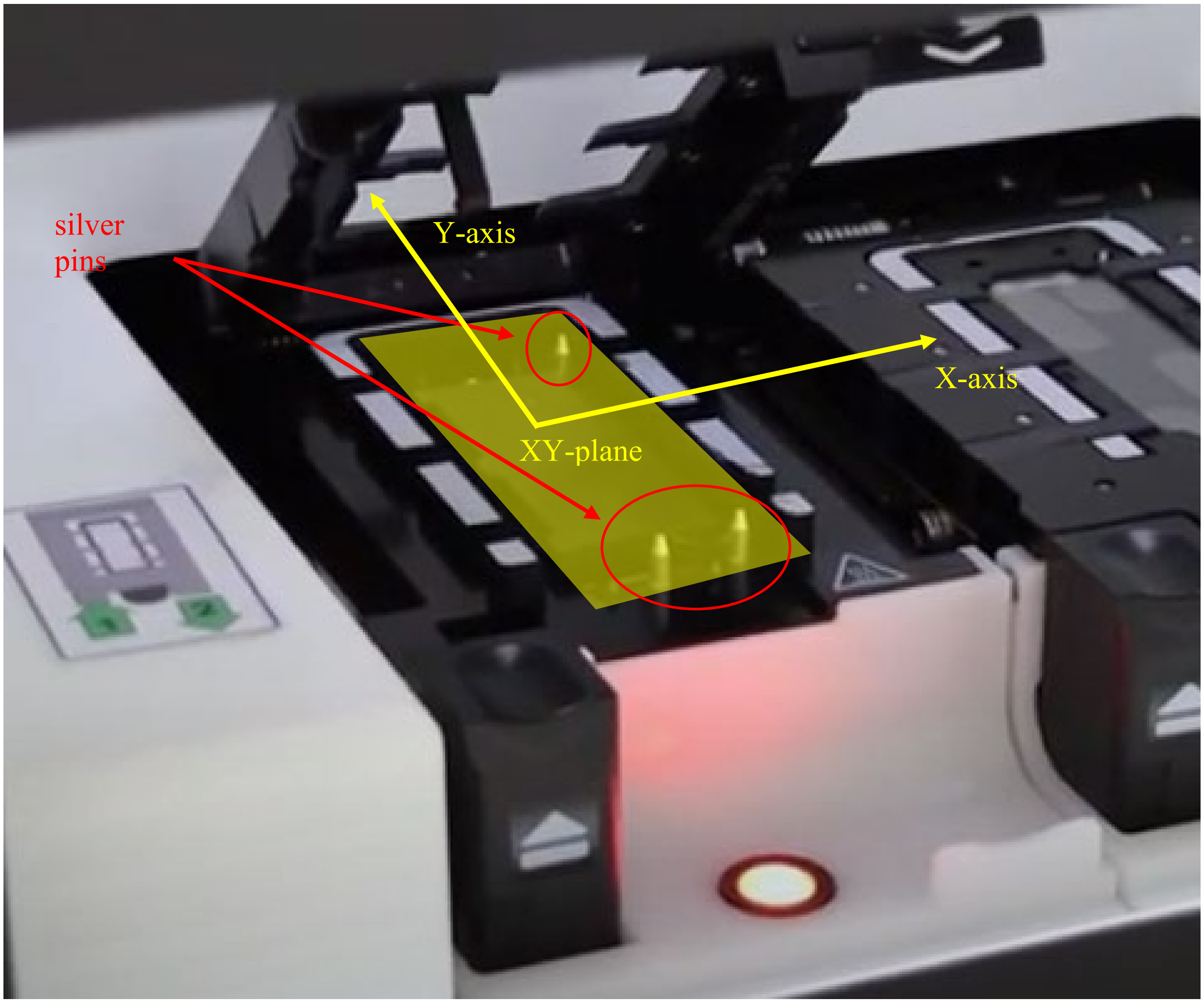
FIG. 18

(Ex. 3, ’781 Patent at Fig. 18 (annotated).)

115. The ’781 Patent further discloses that, in this embodiment, “[t]he alignment members **431-433** have corresponding reference surfaces that are configured to engage the flow cell **200** and facilitate positioning the flow cell **200** for imaging. For example, the reference surfaces of the alignment members **431–433** may face in respective directions along the XY-plane and, as such, may be configured to limit movement of the flow cell **200** along the XY-plane.” (Ex. 3, ’781 Patent at 30:25–32.) In other words, in this embodiment, the faces of the

alignment members in the XY-plane that limit movement of the flow cell in that plane are "reference surfaces."

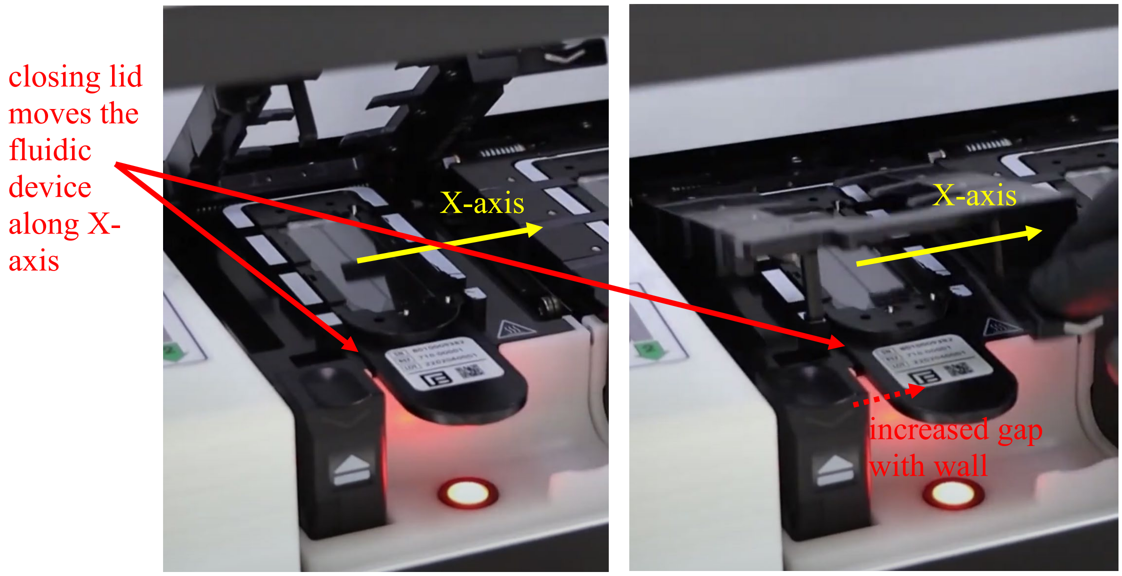
116. Element's AVITI Systems include a plurality of reference surfaces facing in respective directions along an XY-plane, as recited in Claim 30 of the '781 Patent. Element's AVITI Systems include the same plurality of reference surfaces as the embodiment in Figure 18 of the '781 Patent. Each nest in the AVITI Systems comprises three silver pins that fit into corresponding holes in the plastic cartridge housing the flow cell (together, the fluidic device), as shown in the image below. These silver pins limit the movement of the fluidic device along the XY-plane. (*See* Ex. 24, AVITI System Workflow Guide at 13 ("Three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge, ensuring proper alignment and seating."); Ex. 22, AVITI24 System User Guide at 8 ("To ensure proper alignment, three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge.").) These faces of the three silver pins (*i.e.*, the surfaces that make up the round sides of the pins, as opposed to their pointed tops) are therefore a plurality of reference surfaces facing in respective directions along an XY-plane.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

117. "an alignment assembly comprising an actuator and a movable locator arm that is operatively coupled to the actuator, the locator arm having an engagement end, the actuator moving the locator arm between retracted and biased positions to move the engagement end away from and toward the reference surfaces." Element's AVITI Systems have an alignment assembly as recited in Claim 30 of the '781 Patent. According to Element's AVITI product guides, each

nest contains a nest lid coupled to a mechanism that secures the fluidic device. (Ex. 24, AVITI System Workflow Guide at 13 ("A tab closes the lid and ***secures the flow cell***." (emphasis added)); Ex. 22, AVITI24 System User Guide at 8 ("A hinged flow cell lid secures the flow cell in place.").) In a video demonstration of the AVITI system, when the operator closes the nest lid, the flow cell and plastic cartridge (the fluidic device) shift to the right (in the direction of the X-axis), as shown by the two screenshots in the image below.



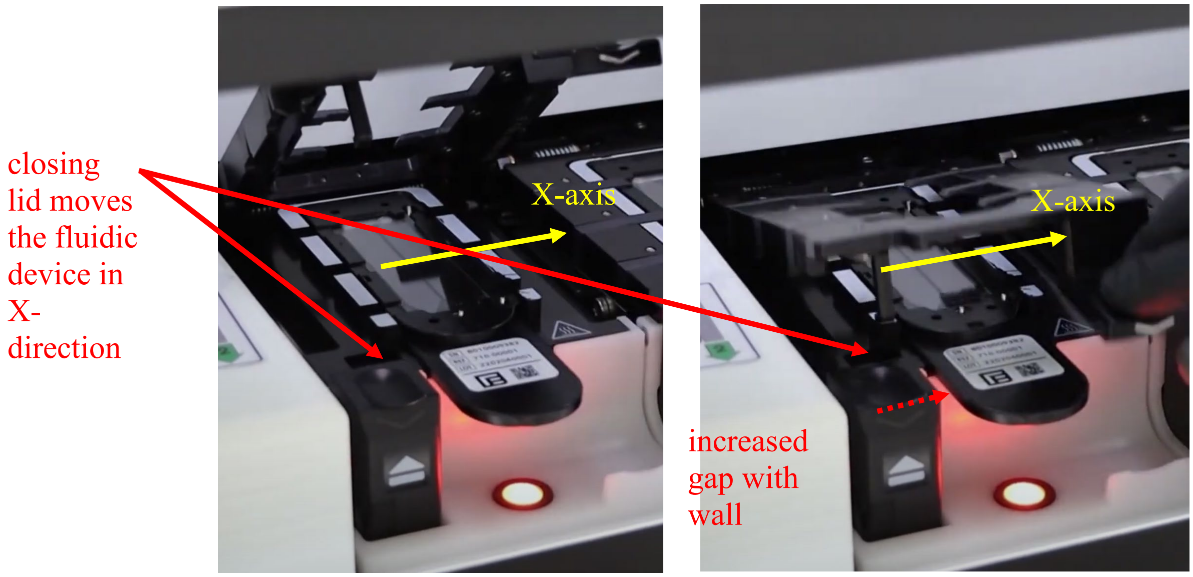
(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:06 (July 21, 2022) (annotated).)

118. In the AVITI Systems, the change in the position of the fluidic device along the X-axis upon closing the lid involves the presence of an actuator applying a force to the fluidic device. The fluidic device shifts position along the X-axis when the nest lid is closed, demonstrating that the actuator is operatively coupled to another component—a movable locator arm—that moves the fluidic

device along the X-axis. In the AVITI Systems, the change in the position of the fluidic device along the X-axis upon closing of the nest lid means that the locator arm has a surface that pushes against the flow cell—the "engagement end." That change in position in the AVITI Systems means that the actuator moves the locator arm between retracted (*i.e.*, not pressing against the fluidic device) and biased (*i.e.*, pressing against the fluidic device) positions to move the engagement end away from and toward the faces of at least some of the three silver pins, the reference surfaces. In the AVITI Systems, the fluidic device moves as shown in the video because when the locator arm is in the biased position it exerts a force on the fluidic device along the X-axis.

119. "wherein the engagement end presses, in a direction along the XY plane, the fluidic device against the reference surfaces when the locator arm is in the biased position such that the fluidic device is held between the engagement end and the reference surfaces in a fixed position with respect to the support structure." The engagement end of the locator arm in Element's AVITI Systems presses the fluidic device against the reference surfaces as recited in Claim 30 of the '781 Patent. According to Element's product guides, closing the lid secures the flow cell and plastic cartridge (together, the fluidic device). (Ex. 24, AVITI System Workflow Guide at 13 ("A tab closes the lid and ***secures the flow cell***." (emphasis added)); Ex. 22, AVITI24 System User Guide at 8 ("A hinged flow cell

lid secures the flow cell in place.").) In the video demonstration of the AVITI system, when the operator closes the nest lid, the fluidic device shifts to the right (in the direction of the X-axis), as shown by the two screenshots in the image below.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:06 (July 21, 2022) (annotated).)

120. The change in the position of the fluidic device along the X-axis upon closing of the nest lid shows that the engagement end of the locator arm presses, in the X direction, the fluidic device against the faces of at least some of the three silver pins (the reference surfaces) when the locator arm is in the biased position (here, pressing against the fluidic device with a force along the X-axis). The fluidic device is held between the engagement end and the reference surfaces in a fixed position with respect to the nest (the support structure) because closing the nest lid places the locator arm in a biased position, causing it to press the

fluidic device against the faces of at least some of the three silver pins (reference surfaces).

121. "the locator arm includes a finger, the finger including the engagement end." The locator arm in Element's AVITI Systems includes a finger as recited in Claim 30 of the '781 Patent. In mechanical engineering, a finger is a projecting machine part. The locator arm in the AVITI Systems has a finger to make contact with the fluidic device to exert a biasing force pressing the fluidic device against the faces of at least some of the three silver pins (the reference surfaces). This finger includes the engagement end, which, in the AVITI Systems, is the part of the locator arm that presses against the fluidic device to ensure proper alignment.

122. As shown above, the AVITI Systems satisfy each and every limitation of Claim 30 of the '781 Patent. The AVITI Systems also satisfy each and every limitation of at least Claims 31, 38–39 and 42–43.

123. In violation of 35 U.S.C. § 271(a), Element has infringed the '781 Patent by making, using, offering to sell and selling the AVITI Systems.

124. In addition to directly infringing, in violation of 35 U.S.C. § 271(b), Element has induced and continues to induce its customers to directly infringe the '781 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on

Element's website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element's customers and prospective customers and/or providing technical support or other services for the products to Element's customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the "fluidic device holder." Element knows that when Element's customers use the AVITI Systems as directed by Element, Element's customers are directly infringing the '781 Patent.

125. Element has been on notice of the infringement alleged in this Count since on or around the issuance of the '781 Patent on February 10, 2015. Alternatively, Element has been on notice of the '781 Patent at least since May 15, 2025, when Illumina filed and served on Element a complaint alleging that Element infringes the '781 Patent. Element has committed acts of infringement willfully and intentionally after notice of infringement.

126. Element purchased a MiSeq instrument from Illumina in February 2019. This instrument included a label noting that the patents associated

with it can be accessed at www.illumina.com/patents. Element used the MiSeq instrument in its development of the AVITI Systems.

127. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT III: INFRINGEMENT OF THE ’130 PATENT

128. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

129. Element has infringed at least Claims 1, 2–7, 10–19 and 21–23 of the ’130 Patent in violation of 35 U.S.C. § 271(a), by making, using, offering to sell and selling within the United States the inventions claimed in the ’130 Patent.

130. Independent Claim 1 of the ’130 Patent recites:

> A system comprising
>
> an optical deck having a plurality of optical components mounted thereto;
>
> a sample deck having a slidable platform that supports a fluidic device thereon and a thermal module to control a temperature of the fluidic device; and
>
> a fluid storage system comprising:
>
> an enclosure having a cavity;
>
> a door configured to open to provide access to the cavity;
>
> a temperature control assembly configured to regulate a temperature within the cavity;
>
> a fluid removal assembly comprising:

> an elevator mechanism including a drive motor, and a stage assembly having a transport platform to hold an array of sipper tubes disposable at least partially within the cavity,
>
> wherein the drive motor is to move the array of sipper tubes bidirectionally along a Z-axis,
>
> wherein each sipper tube of the array of sipper tubes includes a distal portion that is to be inserted into a component well of a reaction component tray such that fluids stored in the reaction component tray are removeable to be delivered to the fluidic device, wherein the enclosure of the fluid storage system is separate from the optical deck and separate from the sample deck; and
>
> a casing enclosing the optical deck and the fluid storage system therein, the door providing access through the casing to the cavity.

(Ex. 4, '130 Patent at 53:38–67.)

131. "A system comprising." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 76–79), the AVITI Systems are systems, which satisfies this limitation of Claim 1 of the '130 Patent.

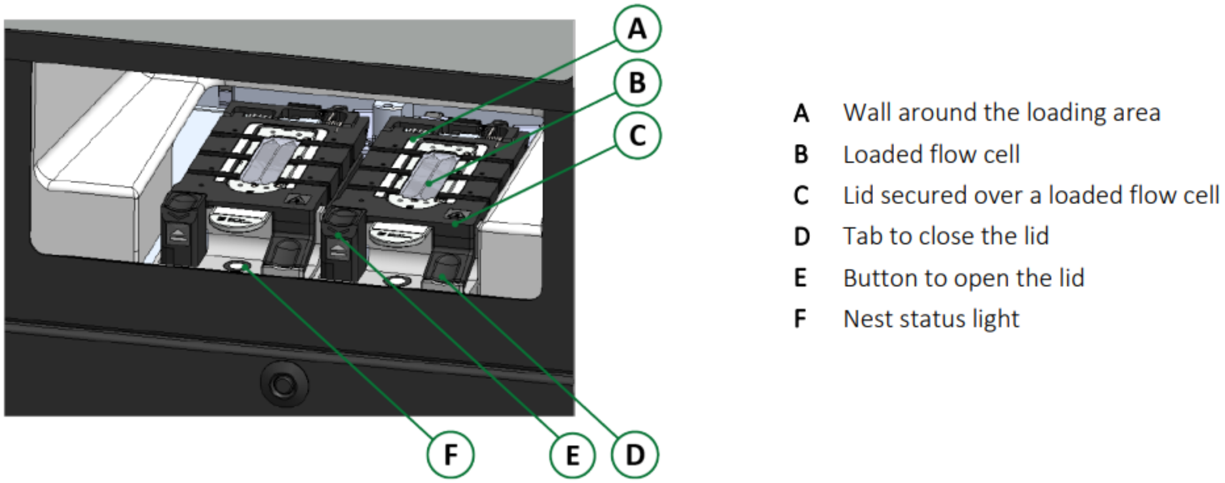
132. "an optical deck having a plurality of optical components mounted thereto." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 80–81), the AVITI Systems have an optical system comprising an excitation light source, an imaging detector and an optical train. This system includes an optical deck, a fixture on which various optical components are mounted. This optical deck is the optical deck recited in Claim 1 of the '130 Patent.

133. The optical system of the AVITI Systems "is a four-color optical system with two excitation lines of approximately 532 and 635 nm. The four-color system is created using an ***objective lens***, ***multiple tube lenses and multiple cameras*** for simultaneous imaging of four spectrally separated colors. . . . The instrument contains two fluidics modules and a shared imaging module, enabling parallel utilization of two flowcells." (Ex. 23, Element 2023 Publication at 134 (emphasis added).) The objective lens, the multiple tube lenses and the multiple cameras are a plurality of optical components mounted to an optical deck.

134. "a sample deck having a slidable platform that supports a fluidic device thereon." Element's AVITI Systems have a sample deck having a slidable platform that supports a fluidic device, as recited in Claim 1 of the '130 Patent. The AVITI Systems, inside the nest bay, have a sample deck with a slidable platform with two nests mounted thereto. As described below, each nest supports a fluidic device thereon.

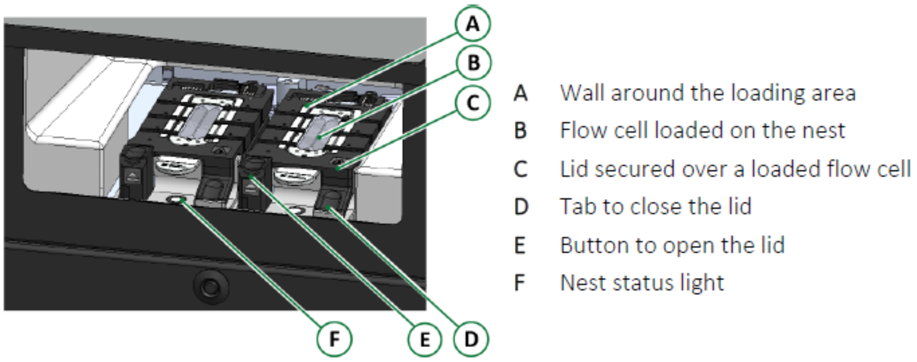
135. The AVITI System Workflow Guide states that "[t]he nest bay includes two nests, one for each side. Each nest holds one flow cell [marked as B below] secured with a lid." (Ex. 24, AVITI System Workflow Guide at 13.) The flow cell, together with its plastic cartridge, is the fluidic device. The figure below

shows the nest bay, which includes the slidable platform, including the two nests, each of which supports a fluidic device thereon.


A
B
C
F
E
D
A Wall around the loading area
B Loaded flow cell
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

(Ex. 24, AVITI System Workflow Guide at 13.)

136. The AVITI24 is structured in the same manner: "The nest bay includes two nests, one for each side, and each nest holds one flow cell [marked as B below]. A hinged flow cell lid secures the flow cell in place." (Ex. 22, AVITI24 System User Guide at 8.)


A
B
C
F
E
D
A Wall around the loading area
B Flow cell loaded on the nest
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

(Ex. 22, AVITI24 System User Guide at 8.)

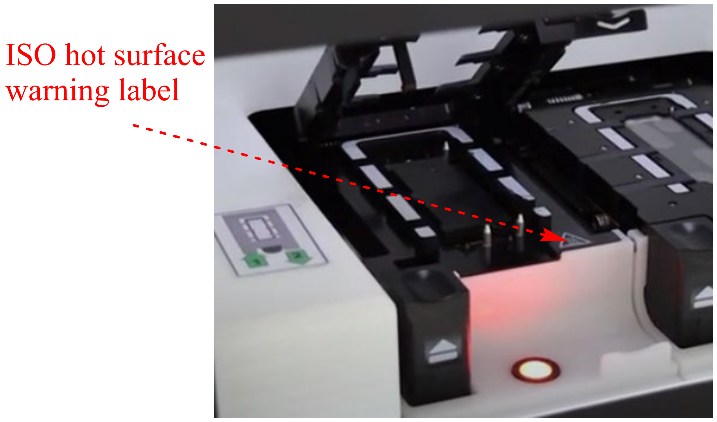
137. In the AVITI Systems, to permit the fluidic device to be imaged, the nests that support the fluidic device are mounted to a slidable platform

on the sample deck. The slidable platform allows the fluidic devices to be positioned for optical analysis.

138. "a thermal module to control a temperature of the fluidic device." In the AVITI Systems, the sample deck has a thermal module, such as a thermoelectric cooler ("TEC") to control a temperature of the fluidic device, as recited in Claim 1 of the '130 Patent.

139. The AVITI System Workflow Guide states that "[t]he nest has a hot surface and exposure can cause burns." (Ex. 24, AVITI System Workflow Guide at 91.) The AVITI24 System User Guide similarly states that "[t]he nest has a hot surface and exposure can cause burns." (Ex. 22, AVITI24 System User Guide at 59.) Thus, the nest, which is on the slidable platform on the sample deck, has a thermal module (such as a thermoelectric cooler, which is capable of heating) to control a temperature of the respective fluidic device that is placed on each nest.

140. As can be seen from the screenshot of Element's AVITI system demonstration video below, the AVITI Systems have the hot surface warning label, which further shows that the sample deck has a thermal module to control a temperature of the fluidic device.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

141. "a fluid storage system comprising." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶ 89), the AVITI Systems have a fluid storage system, which satisfies this limitation of Claim 1 of the '130 Patent. The fluid storage system is the collection of components of the AVITI Systems that store and distribute the reagents and washes. It includes the pump bay, the reagent bay, the sequencing cartridge, the system of movable sipper tubes, and the refrigeration system.

142. "an enclosure having a cavity." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 90–92), Element's AVITI Systems' fluid storage systems include an enclosure having a cavity, as recited in Claim 1 of the '130 Patent. The enclosure contains at least the reagent bay on each side of the AVITI Systems, and the cavity is the interior of the enclosure.

143. "a door configured to open to provide access to the cavity." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶ 93), the AVITI Systems include a fluid storage system with a reagent bay door configured to open to provide access to the cavity. This reagent bay door is the door recited in Claim 1 of the '130 Patent. The reagent bay doors are openable to provide access to the cavity.

144. "a temperature control assembly configured to regulate a temperature within the cavity." Element's AVITI Systems' fluid storage system has a temperature control assembly configured to regulate a temperature within the cavity, as recited in Claim 1 of the '130 Patent.

145. In Element's AVITI Systems, the sequencing cartridge contains the reagents for sequencing. These cartridges are sold frozen and must be thawed. A thawed, ready-for-use sequencing cartridge is stored at 2°C to 8°C. (Ex. 24, AVITI System Workflow Guide at 44 ("If you are not sequencing immediately, keep the [sequencing] cartridge at 2°C to 8°C.").)

146. The AVITI product guides instruct the user: "Each reagent bay holds a buffer bottle and cartridge basket that contains a [sequencing] cartridge or a wash tray, depending on whether the system is sequencing or washing. Keep the reagent bay doors closed ***to maintain the refrigeration, which chills reagents***."

(Ex. 9, AVITI System User Guide at 9 (emphasis added); Ex. 22, AVITI24 System User Guide at 9 (same).)

147. Thus, the system in the AVITI Systems that stores and distributes reagents and wash solutions (the fluid storage system) includes a temperature control assembly configured to maintain the refrigeration (regulate a temperature) within the cavity.

148. "a fluid removal assembly comprising." The AVITI Systems' fluid storage system includes a fluid removal assembly, as recited by Claim 1 of the '130 Patent. The AVITI Systems have an assembly to remove fluids (reagents and washes) from the reagent bay. The AVITI System Workflow Guide states: "When priming starts, sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well. The sippers continue to aspirate reagents throughout the run. Functioning similarly for a wash, the sippers aspirate wash solution instead of reagents." (Ex. 24, AVITI System Workflow Guide at 14; *see also* Ex. 22, AVITI24 System User Guide at 9 (same).)

149. "an elevator mechanism including a drive motor." Element's AVITI Systems' fluid removal assembly has an elevator mechanism including a drive motor, as recited in Claim 1 of the '130 Patent. The '130 Patent describes an embodiment in which the elevator mechanism is "configured to move components

of the removal assembly **1022** bi-directionally along the Z-axis." (Ex. 4, '130 Patent at 36:32–34.) The array of sipper tubes in the AVITI Systems (described below) ascend and descend (*i.e.*, move bi-directionally along the Z-axis) into the bay to aspirate reagents from the sequencing cartridges. In the AVITI Systems, for the sippers to descend into the reagent bay and pierce the foil seals, the fluid removal system uses an elevator mechanism including a drive motor to move the sipper tubes up and down into the reagent bay.

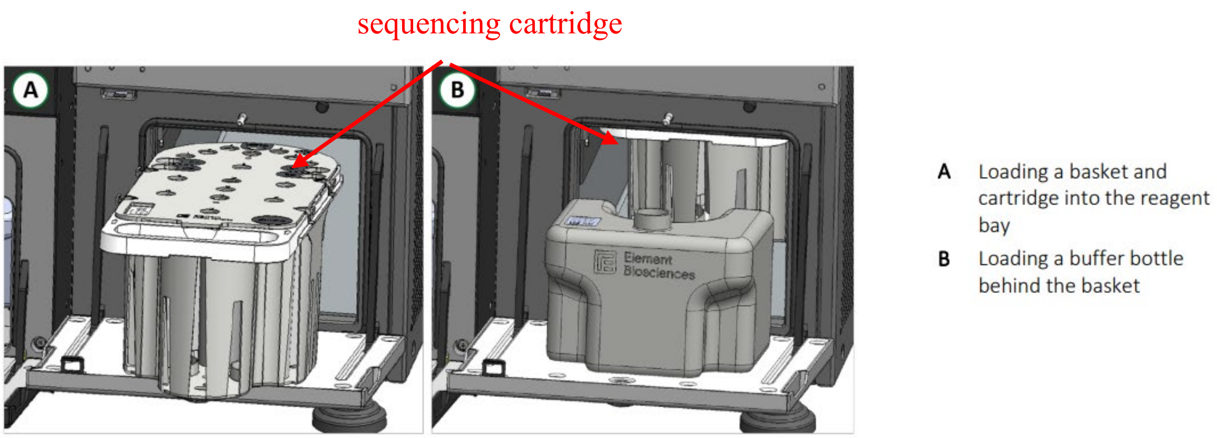
150. "a stage assembly having a transport platform to hold an array of sipper tubes disposable at least partially within the cavity." Element's AVITI Systems include a stage assembly having a transport platform to hold an array of sipper tubes disposable at least partially within the cavity, as recited in Claim 1 of the '130 Patent.

151. The '130 Patent describes an embodiment in which the stage assembly is the component of the fluid removal assembly that moves up and down as part of the elevator mechanism. (Ex. 4, '130 Patent at 36:61–64, 37:1–4, 37:23–27.) The patent further describes an embodiment in which the transport platform is the part of the stage assembly "configured to hold an array of sipper tubes." (*Id.* at 36:61–64, 37:5–6.) The AVITI Systems include a stage assembly having a transport platform to hold an array of sipper tubes to cause the sipper tubes to descend into the reagent bay. (Ex. 24, AVITI System Workflow Guide at 14

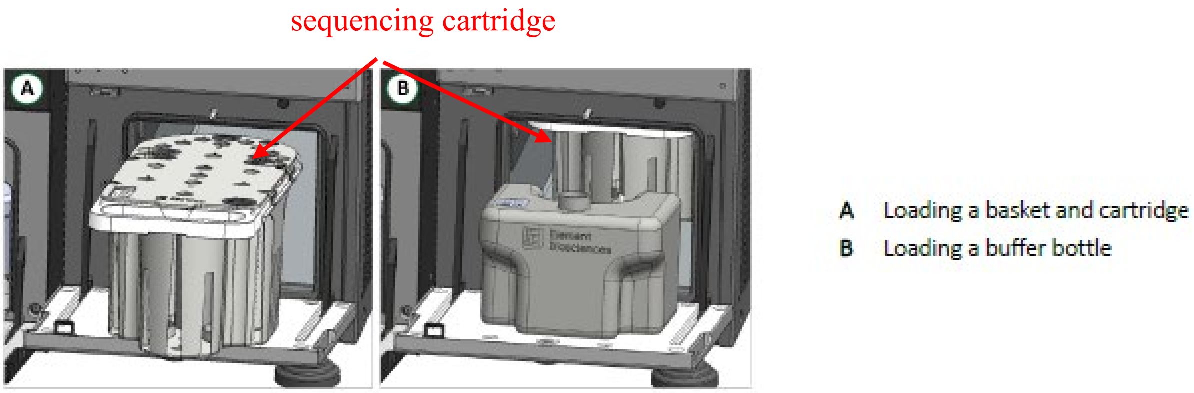
("When priming starts, sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well."); Ex. 22, AVITI24 System User Guide at 9 (same).)

152. As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 94–95), Element's AVITI Systems include a transport platform holding the array of sipper tubes, each sipper tube of the array of sipper tubes including a distal portion positioned to be inserted into a component well of a sequencing cartridge within the cavity. This transport platform is the transport platform to hold an array of sipper tubes disposable at least partially within the cavity recited in Claim 1 of the '130 Patent.

153. The sequencing cartridge in the AVITI Systems is located within the reagent bay (a part of the cavity). (Ex. 9, AVITI System User Guide at 9 ("Each reagent bay holds a buffer bottle and cartridge basket that contains a [sequencing] cartridge or a wash tray, depending on whether the system is sequencing or washing."); Ex. 22, AVITI24 System User Guide at 9 (same).) In the AVITI Systems, the sipper tubes descend into the reagent bay to be inserted into the sequencing cartridge. Thus, the sipper tubes are disposable at least partially within the cavity to aspirate reagents. The opening of the cavity containing the sequencing cartridge from which the sipper tubes will aspirate reagents is shown in the image below.


sequencing cartridge
A
B
Element Biosciences
A Loading a basket and cartridge into the reagent bay
B Loading a buffer bottle behind the basket

(Ex. 24, AVITI System Workflow Guide at 15 (figure titled "Open reagent bay with reagents") (annotated).)


sequencing cartridge
A
B
A Loading a basket and cartridge
B Loading a buffer bottle

(Ex. 22, AVITI24 System User Guide at 9 (annotated).)

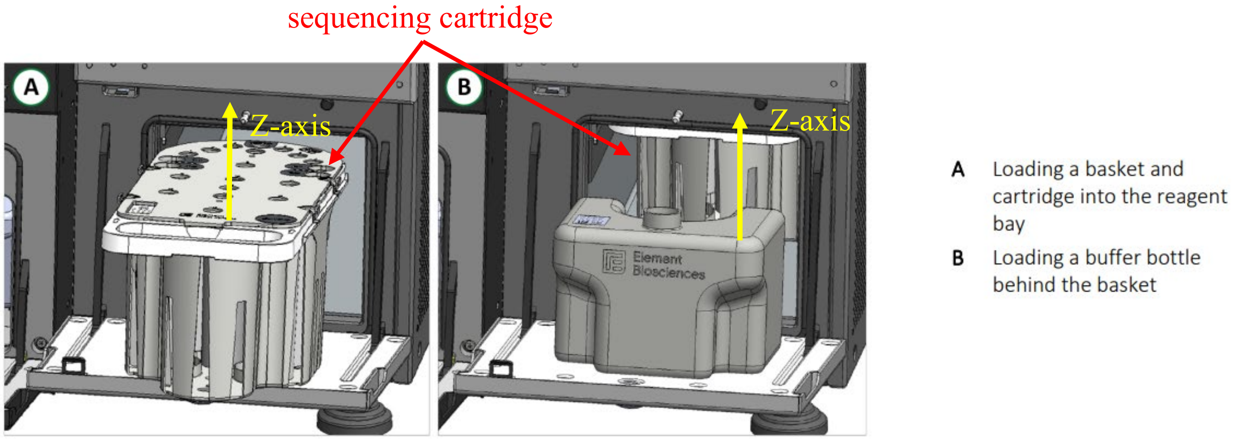
154. "wherein the drive motor is to move the array of sipper tubes bidirectionally along a Z-axis." Element's AVITI Systems have a drive motor, wherein the drive motor is to move the array of sipper tubes bidirectionally along a Z-axis, as recited in Claim 1 of the '130 Patent.

155. The AVITI System Workflow Guide states that the sippers (sipper tubes) descend into the sequencing cartridge to aspirate (remove) the reagents from the sequencing cartridge: "When priming starts, sippers descend into

the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well." (Ex. 24, AVITI System Workflow Guide at 14; *see also* Ex. 22, AVITI24 System User Guide at 9 (same).) The array of sipper tubes is moved by the drive motor downward along the Z-axis to pierce the foil seals covering the sequencing cartridge wells.

156. After the instrument has completed its run and a new cartridge is to be inserted, the sippers (sipper tubes) in the AVITI Systems return to their original position (*i.e.*, move upward along the Z-axis) so that the used sequencing cartridge may be removed and another cartridge may be inserted. Again, the drive motor moves the array of sipper tubes upward along the Z-axis.

157. The drive motor thus is used to move the array of sipper tubes bidirectionally along the Z-axis. The below image shows the sequencing cartridges, and a yellow arrow shows the Z-axis.


sequencing cartridge
A
Z-axis
B
Z-axis
Element Biosciences
A Loading a basket and cartridge into the reagent bay
B Loading a buffer bottle behind the basket

(Ex. 24, AVITI System Workflow Guide at 15 (figure titled "Open reagent bay with reagents") (annotated).)

158. "wherein each sipper tube of the array of sipper tubes includes a distal portion that is to be inserted into a component well of a reaction component tray such that fluids stored in the reaction component tray are removeable to be delivered to the fluidic device." As alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 94–95), the sipper tubes of the array of sipper tubes in the AVITI Systems include a distal portion positioned to be inserted into a component well of a reaction tray within the cavity. These sipper tubes are the sipper tubes recited in Claim 1 of the '130 Patent, and for the same reasons, each sipper tube of the array of sipper tubes includes a distal portion that is to be inserted into a component well of a sequencing cartridge (the reaction component tray) such that fluids stored in the reaction component tray are removeable to be delivered to the fluidic device, as recited in Claim 1 of the '130 Patent.

159. "wherein the enclosure of the fluid storage system is separate from the optical deck and separate from the sample deck." Element's AVITI Systems comprise a fluid removal system wherein the enclosure of the fluid storage system is separate from the optical deck and separate from the sample deck, as recited in Claim 1 of the '130 Patent.

160. The enclosure of the system that stores and distributes reagents and washes (the fluid storage system) in the AVITI Systems is separate from the deck to which optical components are attached (the optical deck) and the sample

deck. The below image of the entire AVITI system shows the locations of the reagent bays and the sample deck, which are separate from each other. The optical deck is separate from the fluid storage system as well.

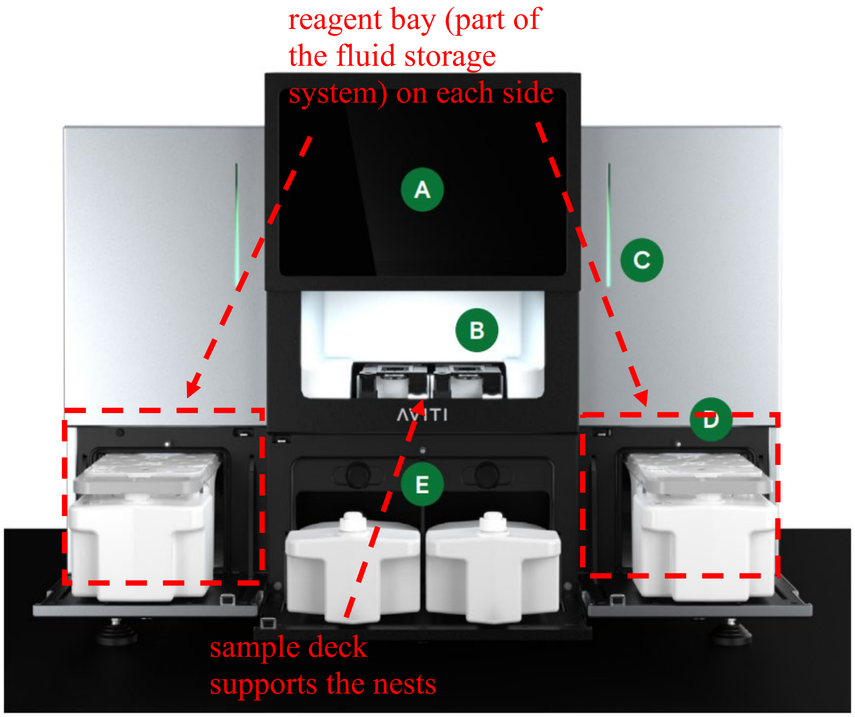


Figure 5. A centralized touchscreen monitor (A) simplifies operations. Nests hold two flow cells (B), one for each side, and an LED display (C) communicates the status of a side. The reagents (D) and waste bottles (E) smoothly load and unload from the instrument.

(Ex. 21, AVITI System Specification Sheet (2023) at 4 (green annotations in original, red annotations added).)

161. "a casing enclosing the optical deck and the fluid storage system therein, the door providing access through the casing to the cavity." Element's AVITI Systems have a casing enclosing the optical deck and the fluid storage system therein, the door providing access through the casing to the cavity, as recited in Claim 1 of the '130 Patent.

162. The AVITI System Workflow Guide states that "[e]xterior shells enclose the instrument to maintain internal temperatures, exclude dust and other external elements, and protect operators from exposure to lasers, mechanical moving parts, and other internal hazards." (Ex. 24, AVITI System Workflow Guide at 12.) The exterior shells are the casing enclosing the optical deck and the fluid storage system.

163. The below images show the casing that encloses the optical deck and the fluid storage system, and the doors that provide access through the casing to the cavity:

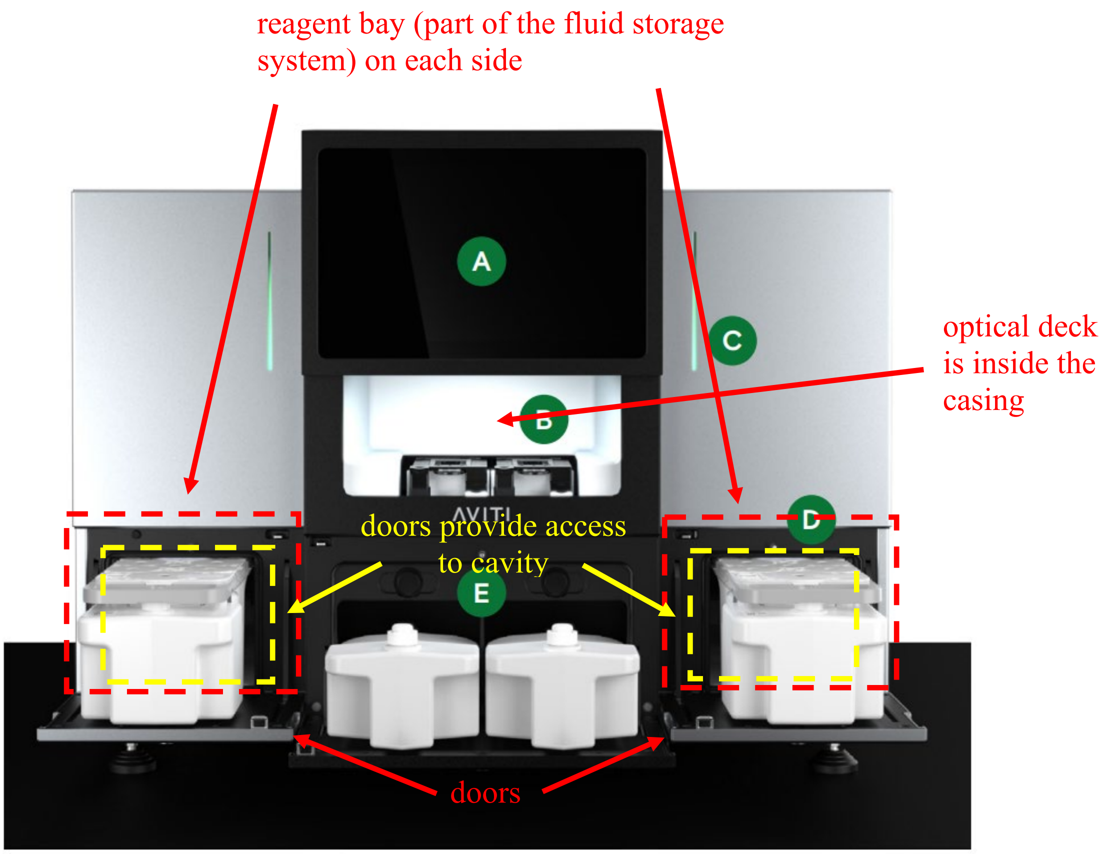
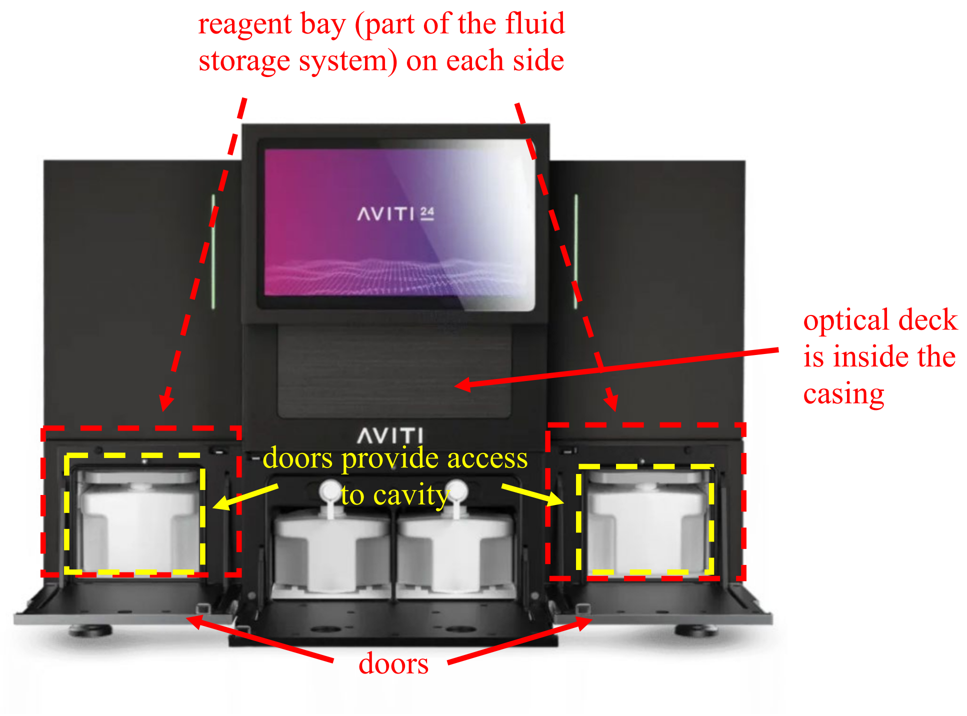

reagent bay (part of the fluid storage system) on each side
A
C
optical deck is inside the casing
B
AVITI
D
doors provide access to cavity
E
doors

Figure 5. A centralized touchscreen monitor (A) simplifies operations. Nests hold two flow cells (B), one for each side, and an LED display (C) communicates the status of a side. The reagents (D) and waste bottles (E) smoothly load and unload from the instrument.

(Ex. 21, Element AVITI System Specification Sheet (2023) at 4 (green annotations in original, red and yellow annotations added).)


reagent bay (part of the fluid storage system) on each side
optical deck is inside the casing
AVITI 24
AVITI
doors provide access to cavity
doors

(Ex. 29, "AVITI24 System and Specifications," https://www.elementbiosciences.com/products/aviti24/platform (annotated).)

164. As shown above, the AVITI Systems satisfy each and every limitation of Claim 1 of the '130 Patent. The AVITI Systems also satisfy each and every limitation of at least Claims 2–7, 10–19 and 21–23.

165. In violation of 35 U.S.C. § 271(a), Element has infringed the '130 Patent by making, using, offering to sell and selling the AVITI Systems.

166. In violation of 35 U.S.C. § 271(b), Element has induced and continues to induce its customers to directly infringe the '130 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on Element's website; establishing distribution channels for these products in the United States; drafting, distributing or making

available product specifications, instructions or user manuals for the products to Element's customers and prospective customers and/or providing technical support or other services for the products to Element's customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the "sample deck having a slidable platform that supports a fluidic device thereon," and loading reagents and fluids into the reagent bay (Ex. 24, AVITI System Workflow Guide at 51–52; Ex. 22, AVITI24 System User Guide at 30–32), thereby making use of the "fluid storage system." Element knows that when Element's customers use the AVITI Systems as directed by Element, Element's customers are directly infringing the '130 Patent.

167. Element has been on notice of the infringement alleged in this Count since on or around the issuance of the '130 Patent on September 14, 2021. Alternatively, Element has been on notice of the '130 Patent at least since May 15, 2025, when Illumina filed and served on Element a complaint alleging that Element infringes the '130 Patent. Element has committed acts of infringement willfully and intentionally after notice of infringement.

168. Element purchased a MiSeq instrument from Illumina in February 2019. This instrument included a label noting that the patents associated

with it can be accessed at www.illumina.com/patents. Element used the MiSeq instrument in its development of the AVITI Systems.

169. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT IV: INFRINGEMENT OF THE '116 PATENT

170. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

171. Element has infringed at least Claim 1 of the '116 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell and selling within the United States the invention claimed in the '116 Patent.

172. Independent Claim 1 of the '116 Patent recites:

> A DNA sequencing instrument comprising:
>
> an optical deck comprising a light source assembly and two imaging detectors;
>
> a sample deck comprising a slidable platform configured to support a fluidic device comprising a flow cell, the sample deck further comprising a thermal module configured to control a temperature of the flow cell;
>
> a fluid storage system comprising:
>
> an enclosure having a cavity;
>
> a door configured to open to provide access to the cavity;
>
> a temperature control assembly configured to regulate a temperature within the cavity, the temperature control assembly comprising a thermoelectric cooling assembly located at a rear of the cavity opposite the door;

a fluid removal assembly comprising:

an elevator mechanism including a drive motor and a lead screw operatively coupled to the drive motor,

a transport platform carrying a flag and configured to hold an array of sipper tubes, the elevator mechanism configured to move the array of sipper tubes bi-directionally between a withdrawn level and a deposited level,

a guide plate having openings through which the array of sipper tubes slide,

a plurality of support beams coupled to the guide plate and extending parallel to the lead screw, and

a location sensor configured to determine a level of the array of sipper tubes;

a reaction component tray within the cavity of the enclosure of the fluid storage system, wherein the reaction component tray comprises a plurality of component wells configured to store fluids, wherein the plurality of component wells include a polymerase, modified nucleotides, a cleavage mix, and an oxidizing protectant; and

a pump configured to direct the flow of fluids from the reaction component tray through the array of sipper tubes to a multi-port valve, the multi-port valve configured to selectively flow the fluids from the reaction component tray to the sample deck during DNA sequencing on the flow cell,

wherein rotation of the lead screw in a first direction moves the transport platform toward the guide plate until the array of sipper tubes is at the deposited level, wherein rotation of the lead screw in a second, opposite direction moves the transport platform away from the guide plate until the array of sipper tubes is at the withdrawn level, wherein sipper tubes of the array of sipper tubes include distal portions that are inserted into component wells of the reaction component tray when the array of sipper tubes is at the deposited level, wherein the distal portions of the sipper tubes are completely removed from the component wells when the array of sipper tubes is at the withdrawn level, and wherein the location sensor is configured

> to detect the flag and determine when the array of sipper tubes has not reached a threshold level such that the reaction component tray is not ready for removal from the cavity.

(Ex. 5, ’116 Patent at 53:28–54:26.)

173. “A DNA sequencing instrument comprising.” The AVITI Systems are DNA sequencing instruments as recited in Claim 1 of the ’116 Patent. The User Guides for the AVITI Systems repeatedly refer to these devices as instruments. (*See, e.g.*, Ex. 9, AVITI System User Guide at 7 (“The ***instrument*** is divided into two sides, side A on the left and side B on the right when facing the ***instrument***.” (emphasis added)); Ex. 22, AVITI24 System User Guide at 7 (same).)

174. The AVITI System Workflow Guide states that the AVITI system is an instrument for conducting DNA sequencing: “The Element AVITI System is a mid-throughput next-generation sequencing (NGS) system that amplifies and ***sequences DNA libraries***.” (Ex. 24, AVITI System Workflow Guide at 6 (emphasis added).)

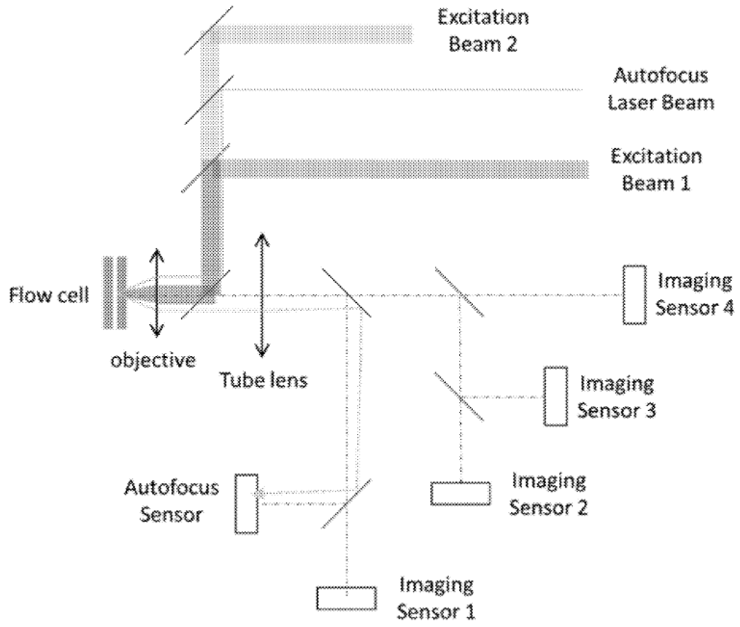
175. Similarly, the AVITI24 System User Guide states: “For ***sequencing runs***, the AVITI24 System is compatible with ***single-strand DNA (ssDNA) libraries*** prepared with particular library preparation workflows and that use Element sequencing chemistry.” (Ex. 22, AVITI24 System User Guide at 6 (emphasis added).)

176. "an optical deck comprising a light source assembly and two imaging detectors." The AVITI Systems have an optical deck with a light source assembly and at least two imaging detectors, as recited in Claim 1 of the '116 Patent.

177. The optical deck includes a light source assembly and at least two imaging detectors. The Element 2023 Publication states:

> Avidity sequencing was performed on the AVITI commercial sequencing system. Briefly, the instrument is a four-color optical system ***with two excitation lines of approximately 532 and 635 nm***. The four-color system is created using an objective lens, multiple tube lenses and ***multiple cameras for simultaneous imaging*** of four spectrally separated colors. . . . The instrument contains two fluidics modules and a shared imaging module, enabling parallel utilization of two flowcells.

(Ex. 23, Element 2023 Publication at 134 (emphases added).) As discussed previously, the components described above are illustrated in Figure 18 from Element's '608 Patent—which purportedly covers the AVITI Systems.


Excitation
Beam 2
Autofocus
Laser Beam
Excitation
Beam 1
Flow cell
objective
Tube lens
Imaging
Sensor 4
Imaging
Sensor 3
Autofocus
Sensor
Imaging
Sensor 2
Imaging
Sensor 1

(Ex. 25, ’608 Patent at Fig. 18.)

The light source assembly emits light at wavelengths of approximately 532 and 635 nm. Two of the four cameras (the imaging sensors shown in the figure above) are the two imaging detectors recited in Claim 1. The light source assembly and the cameras (the imaging detectors) are mounted on the optical deck.

178. “a sample deck comprising a slidable platform configured to support a fluidic device comprising a flow cell.” As previously alleged in regard to Claim 1 of the ’130 Patent (*see supra* ¶¶ 134–137), the AVITI Systems have a sample deck having a slidable platform that supports a fluidic device thereon. In addition, the AVITI Systems include a flow cell and plastic cartridge (together, the fluidic device). (*See* Ex. 24, AVITI System Workflow Guide at 32 (“The flow cell is a two-lane glass substrate encased in a plastic cartridge.”); *see also* Ex. 22, AVITI24 System User Guide at 13 (same).) Thus, this sample deck is the sample

deck comprising a slidable platform configured to support a fluidic device comprising a flow cell recited in Claim 1 of the ’116 Patent.

179. “the sample deck further comprising a thermal module configured to control a temperature of the flow cell.” As previously alleged in regard to Claim 1 of the ’130 Patent (*see supra* ¶¶ 138–140), the sample deck includes a thermal module. Because the thermal module is configured to control a temperature of the fluidic device and because the fluidic device comprises a flow cell, this is the thermal module configured to control the temperature of the flow cell recited in Claim 1 of the ’116 Patent.

180. “a fluid storage system comprising.” As previously alleged in regard to Claim 1 of the ’241 Patent and Claim 1 of the ’130 Patent (*see supra* ¶¶ 89, 141), the AVITI Systems have a fluid storage system, as recited in Claim 1 of the ’116 Patent. The fluid storage system is the collection of components of the AVITI Systems that store and distribute the reagents and washes. It includes the pump bay, the reagent bay, the sequencing cartridge, the system of movable sipper tubes, and the refrigeration system.

181. “an enclosure having a cavity.” As previously alleged in regard to Claim 1 of the ’241 Patent and Claim 1 of the ’130 Patent (*see supra* ¶¶ 90–92, 142), the AVITI Systems have an enclosure having a cavity, as recited in Claim 1

of the ’116 Patent. The claimed enclosure contains at least the reagent bay. Inside the enclosure is the cavity.

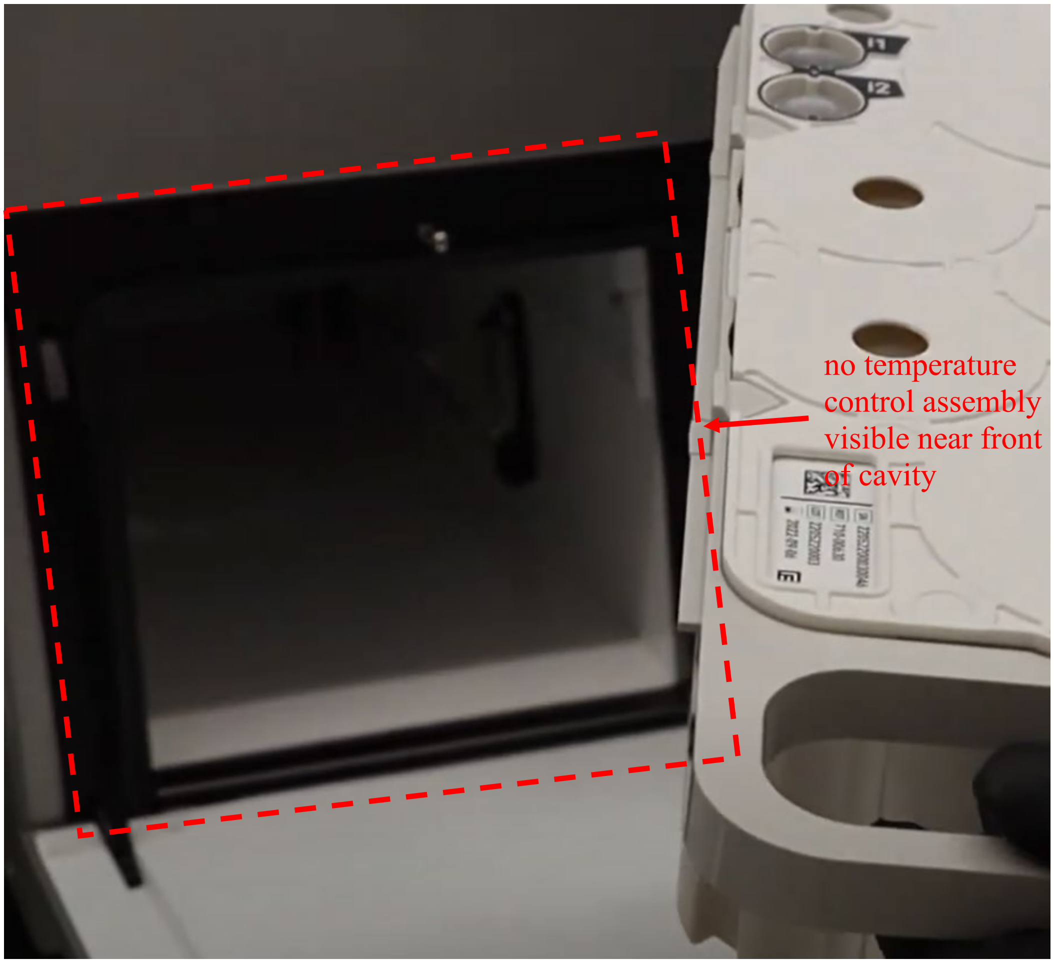
182. “a door configured to open to provide access to the cavity.” As previously alleged in regard to Claim 1 of the ’241 Patent and Claim 1 of the ’130 Patent (*see supra* ¶¶ 93, 143), the AVITI Systems have a reagent bay door configured to open to provide access to the cavity, which is the door configured to open to provide access to the cavity as recited in Claim 1 of the ’116 Patent.

183. “a temperature control assembly configured to regulate a temperature within the cavity, the temperature control assembly comprising a thermoelectric cooling assembly located at a rear of the cavity opposite the door.” As previously alleged in regard to Claim 1 of the ’130 Patent (*see supra* ¶¶ 144–147), the AVITI Systems have a temperature control assembly configured to regulate a temperature within a cavity, which is the temperature control assembly recited in Claim 1 of the ’116 Patent.

184. The temperature control assembly has a thermoelectric cooling assembly. The AVITI System User Guide instructs the user: “Each reagent bay holds a buffer bottle and cartridge basket that contains a sequencing cartridge or a wash tray, depending on whether the system is sequencing or washing. Keep the reagent bay doors closed ***to maintain the refrigeration, which chills reagents***.” (Ex. 9, AVITI System User Guide at 9 (emphasis added); *see also* Ex. 22,

AVITI24 System User Guide at 9 ("Keep the reagent bay doors closed ***to maintain the refrigeration***, which chills reagents." (emphasis added)).) In addition, the AVITI Systems are powered by electricity. (Ex. 9, AVITI System User Guide at 10 ("When connecting the instrument to power, use only the power cord that Element provides."); *see also* Ex. 22, AVITI24 System User Guide at 10 (same).) Because the AVITI Systems refrigerate reagents and are powered by electricity, the temperature control assembly includes a thermoelectric cooling assembly—a device that employs an electric current to remove heat.

185. The thermoelectric cooling assembly is located at the rear of the cavity opposite the door, rather than at the front of the cavity by the door. The temperature control assembly is not visible from the front of the open cavity, as shown in the image below from an Element demonstration video.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 3:21 (July 21, 2022) (annotated).)

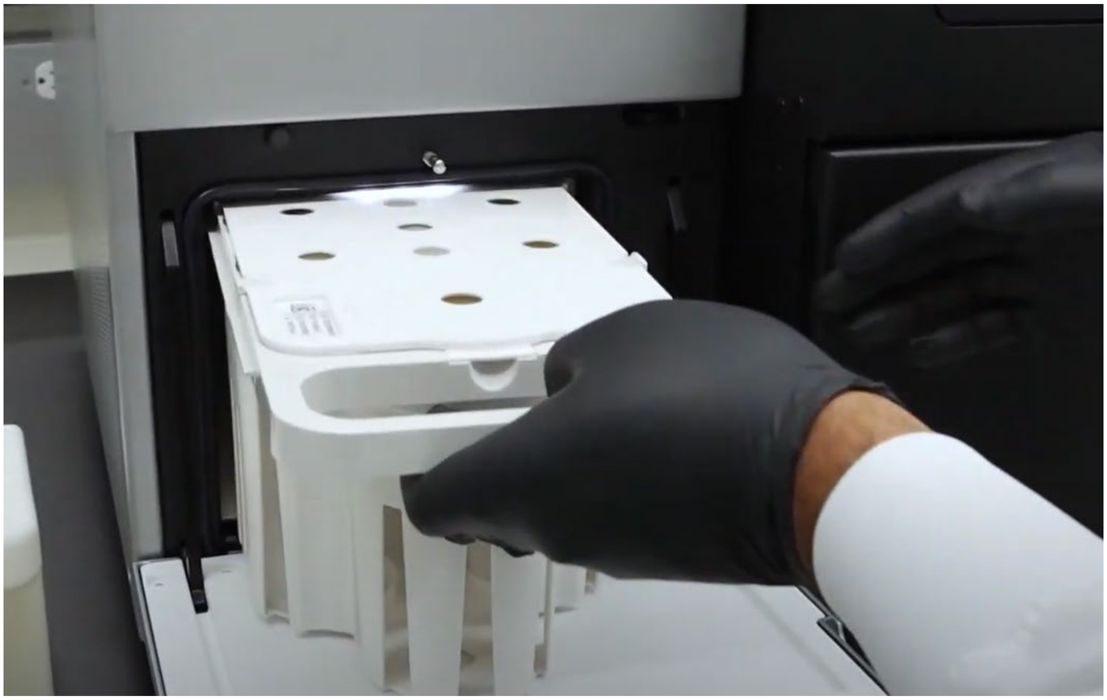
186. "a fluid removal assembly comprising." As previously alleged in regard to Claim 1 of the '130 Patent (*see supra* ¶ 148), the AVITI Systems have a fluid removal assembly, as recited in Claim 1 of the '116 Patent.

187. "an elevator mechanism including a drive motor and a lead screw operatively coupled to the drive motor." As previously alleged in regard to Claim 1 of the '130 Patent (*see supra* ¶ 149), the AVITI Systems have an elevator mechanism including a drive motor. Because a drive motor supplies energy in the

form of rotation, the rotational energy supplied by the drive motor in the AVITI Systems is converted to "linear," or up-and-down, energy before it can be used to move the AVITI Systems' transport platform (discussed below) up and down. In the AVITI Systems, therefore, the drive motor is operatively coupled to a lead screw, which is a device that converts turning motion into linear motion, to allow the drive motor to move the AVITI Systems' transport platform. Thus, the AVITI Systems have an elevator mechanism including a drive motor and a lead screw operatively coupled to the drive motor, as recited in Claim 1 of the '116 Patent.

188. "a transport platform carrying a flag and configured to hold an array of sipper tubes, the elevator mechanism configured to move the array of sipper tubes bi-directionally between a withdrawn level and a deposited level." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 94–95), the AVITI Systems have a transport platform to hold an array of sipper tubes. In addition, as previously alleged in regard to Claim 1 of the '130 Patent (*see supra* ¶¶ 149–157), the AVITI Systems have an elevator mechanism including a drive motor, wherein the drive motor moves an array of sipper tubes bidirectionally along the Z-axis. Thus, the AVITI Systems have a transport platform and an elevator mechanism configured to move the array of sipper tubes bi-directionally, as recited in Claim 1 of the '116 Patent.

189. The AVITI product guides state that the elevator mechanism is configured to move the array of sipper tubes downwards into the sequencing cartridge wells to aspirate reagents from the bottom of the wells, which is the deposited level. (*See* Ex. 24, AVITI System Workflow Guide at 14 ("[S]ippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well."); Ex. 22, AVITI24 System User Guide at 9 (same).) After sequencing, the sequencing cartridge can be removed from the AVITI Systems, as shown in the image below:



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 3:34 (July 21, 2022); *see also* Ex. 22, AVITI24 System User Guide at 31 (directing the user to "[r]emove any materials from the reagent bay").)

For the sequencing cartridge to be removed from the AVITI Systems, the sipper tubes cannot remain inserted into the component wells of the cartridge. Instead, in the AVITI Systems, prior to removal, the sipper tubes are withdrawn upwards to completely exit the sequencing cartridge component wells so that the sequencing cartridge can be withdrawn from the reagent bay without damaging the instrument. The sipper tubes in the AVITI Systems move bi-directionally between a withdrawn level and a deposited level to allow removal of the reaction component tray.

190. For the transport platform to determine when it has ascended or descended to its intended position (for example, when the platform has descended low enough for the sippers to begin aspirating regents from the sequencing cartridge), it registers when the sipper tubes on the transport platform have reached their intended position using a location sensor. The '116 Patent describes an embodiment in which a flag registers the level of the transport platform: "The location sensor may detect a flag **1064** of the stage assembly **1046** to determine a level of the stage assembly **1046**."[3] (Ex. 5, '116 Patent at 37:55–57.) The transport platform in the AVITI Systems includes a flag.

191. "a guide plate having openings through which the array of sipper tubes slide." The '116 Patent discloses that the "guide plate" is a plate that contains openings to prevent misalignment of the sipper tubes with the component wells: "the sipper tubes **1050** include distal portions **1052** that are configured to be

[3] The stage assembly includes the transport platform. Ex. 5, '116 Patent at 36:57–58.

inserted into component wells **1060** . . . of the tray **1020**. The distal portions **1052** extend through corresponding openings **1053** of the guide plate **1040**." (Ex. 5, '116 Patent at 37:3–7.) The patent further discloses that "[t]he guide plate **1040** is configured to prevent distal portions **1052** from becoming misaligned with the component wells **1060** before the distal portions **1052** are inserted therein." (*Id.* at 37:25–28.) As shown in the image below, the guide plate **1040** is configured to keep the distal portions **1052** of the sipper tubes from missing the component wells when the sipper tubes descend.

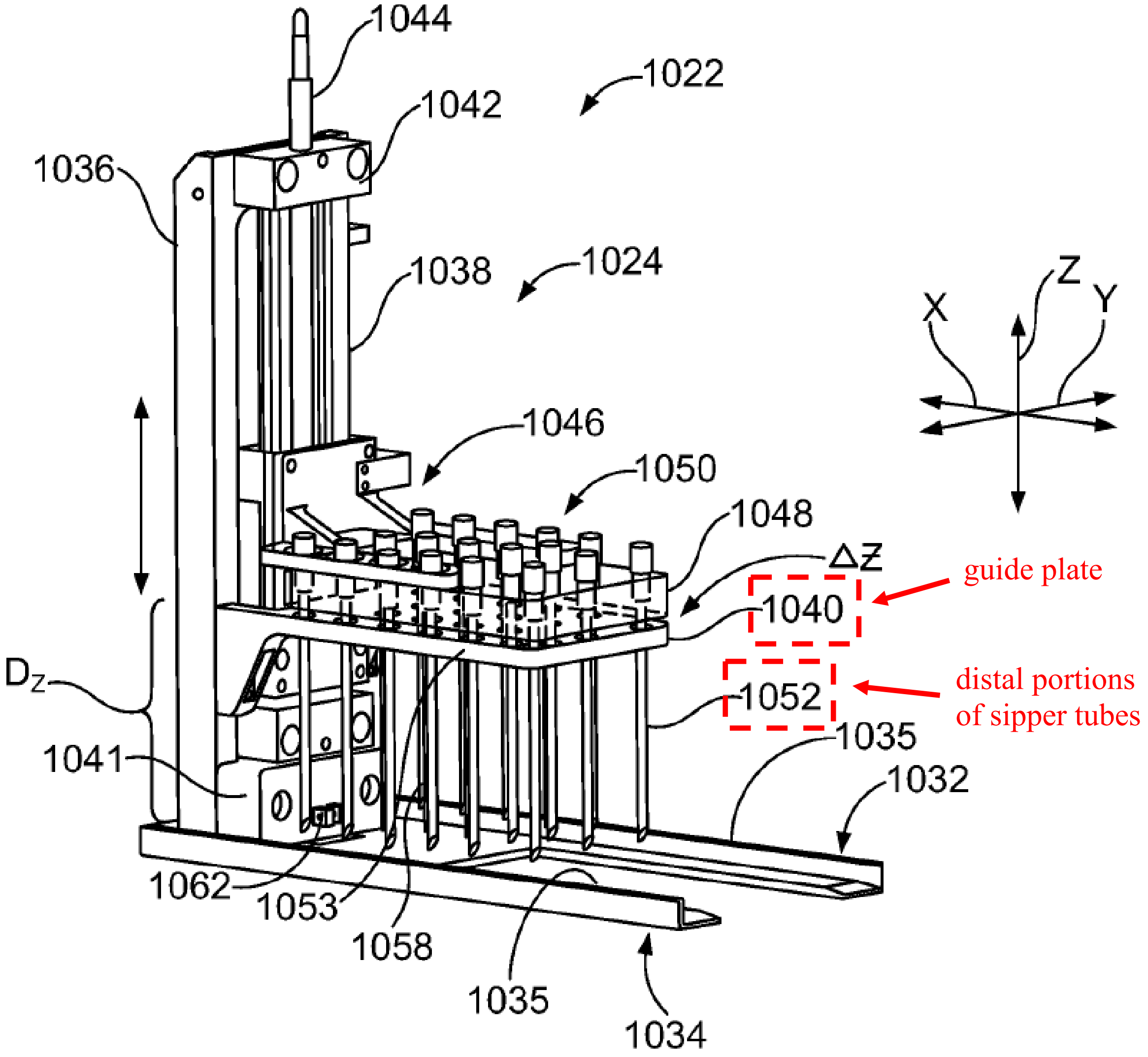

1044
1022
1042
1036
1038
1024
X
Z
Y
1046
1050
1048
ΔZ
guide plate
1040
DZ
1052
distal portions
of sipper tubes
1035
1041
1032
1062
1053
1058
1035
1034

FIG. 30

(Ex. 5, '116 Patent at Fig. 30 (annotated).)

192. The AVITI Systems' fluid removal assembly includes a guide plate having openings through which the array of sipper tubes slide, as recited in Claim 1 of the '116 Patent. "When priming starts, sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well." (Ex. 24, AVITI System

Workflow Guide at 14; Ex. 22, AVITI24 System User Guide at 9 (same).) For the sippers in the AVITI Systems to descend reliably into the cartridge wells, they are aligned with the cartridge wells. The guide plate, which is a plate with openings in it that is positioned over the sequencing cartridge wells, prevents the sipper tubes from becoming misaligned. The array of sipper tubes slides through the corresponding openings of the guide plate when the sippers descend into the bay, so that they pierce the foil seals covering the sequencing cartridge wells.

193. "a plurality of support beams coupled to the guide plate and extending parallel to the lead screw." The AVITI Systems have a plurality of support beams as recited in Claim 1 of the '116 Patent. As previously alleged (*see supra* ¶¶ 191–192), the guide plate within the AVITI Systems rests over the sequencing cartridge when the sequencing cartridge has been loaded into the reagent bay. In this elevated position, the guide plate is attached to the AVITI instruments for support. A plurality of the support beams in the AVITI Systems are coupled to the guide plate. This plurality of support beams extends parallel to the lead screw or is otherwise arranged to perform substantially the same function in substantially the same way to achieve substantially the same result.

194. "a location sensor configured to determine a level of the array of sipper tubes." The AVITI Systems have a location sensor as recited in Claim 1 of the '116 Patent. The '116 Patent describes an embodiment in which the location

sensor determines the level of the array of sipper tubes: "The location sensor may detect a flag **1064** of the stage assembly **1046** to determine a level of the stage assembly **1046**."[4] (Ex. 5, '116 Patent at 37:55–57.) Within the AVITI Systems, the sipper tubes attached to the transport platform move bi-directionally between the deposited position and the withdrawn position to aspirate reagents from the sequencing cartridge (or the wash solution from the wash tray). The AVITI Systems gauge the position of the transport platform using a location sensor. To determine whether the sippers have reached a threshold level where the reaction tray is ready for removal from the cavity, the location sensor detects the position of the flag.

195. "a reaction component tray within the cavity of the enclosure of the fluid storage system, wherein the reaction component tray comprises a plurality of component wells configured to store fluids, wherein the plurality of component wells include a polymerase, modified nucleotides, a cleavage mix, and an oxidizing protectant." The AVITI Systems have a reaction component tray that is configured as recited in Claim 1 of the '116 Patent.

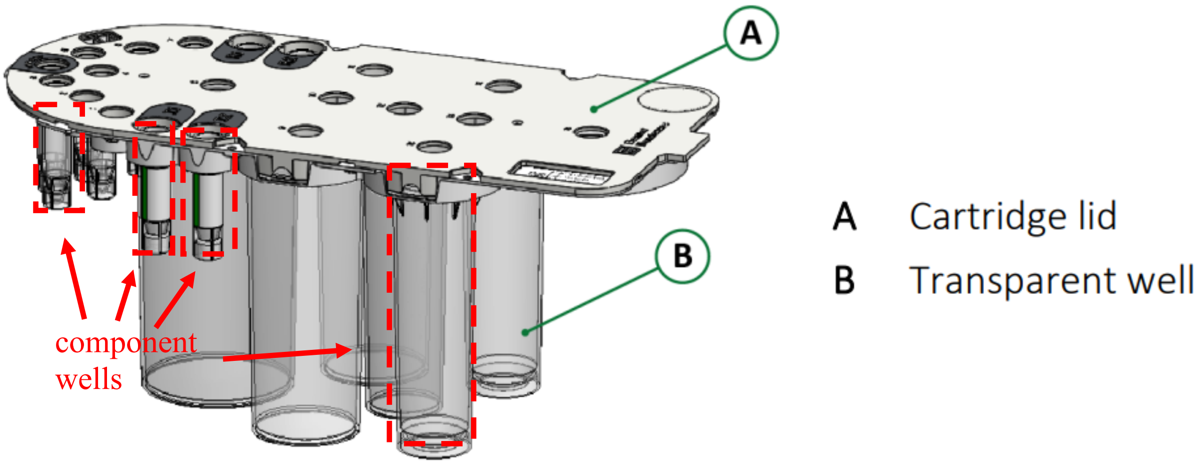
196. In the AVITI Systems, the sequencing cartridge is the reaction component tray. The sequencing cartridge "is a collection of reagents and buffers

[4] The stage assembly includes the transport platform that holds an array of sipper tubes. Ex. 5, '116 Patent at 36:57–58, 36:66–67.

in foil-sealed wells that are packaged in an easy-to-load container." (Ex. 9, AVITI System User Guide at 13; Ex. 22, AVITI24 System User Guide at 13.)

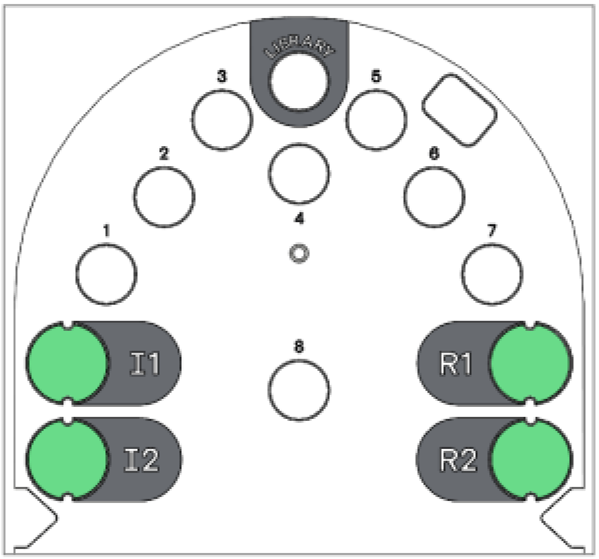
197. The AVITI Systems' sequencing cartridge (the reaction component tray) is located within the cavity of the enclosure of the fluid storage system. As discussed (*see supra* ¶¶ 90–92, 142, 181), the enclosure contains at least the reagent bay of the AVITI Systems. The AVITI product guides state that "[e]ach reagent bay holds a buffer bottle and cartridge basket that contains a [sequencing] cartridge or a wash tray, depending on whether the system is sequencing or washing." (Ex. 9, AVITI System User Guide at 9; *see also* Ex. 22, AVITI24 System User Guide at 9 (same).)

198. In the AVITI Systems, the reaction component tray has a plurality of component wells configured to store fluids. The sequencing cartridge (the reaction component tray) is prefilled with amplification, paired-end, indexing and cycling reagents for sequencing and buffer for the post-run wash. "Each reagent occupies a foil-sealed well." (Ex. 24, AVITI System Workflow Guide at 31.) The sequencing cartridge, with some of the plurality of component wells annotated, is shown below:


A
B
component wells
A Cartridge lid
B Transparent well

(Ex. 9, AVITI System User Guide at 13 (green annotations in original, red annotations added).)

199. A top view of the sequencing cartridge, showing the tops of the component wells, is shown below.


LIBRARY
1
2
3
4
5
6
7
8
I1
I2
R1
R2

(Ex. 24, AVITI System Workflow Guide at 43.)

200. The plurality of component wells in the sequencing cartridge include a polymerase, modified nucleotides, a cleavage mix and an oxidizing protectant, as recited in Claim 1. Element states that the "sequencing cartridge

packages the amplification, paired-end, indexing, and cycling reagents and a post-run wash buffer into a convenient container." (Ex. 24, AVITI System Workflow Guide at 31.) When the AVITI Systems begin a sequencing run, "the library hybridizes to surface primers coating the flow cell. ***Amplification polymerase*** then binds to the library and primer duplexes . . . For each cycle, a ***sequencing polymerase*** binds an avidite to a polony and primer duplex." (Ex. 10, AVITI System Specification Sheet (2024) at 1–2 (emphases added).) Thus, at least one of the plurality of component wells used by the AVITI Systems during sequencing contains a polymerase.

201. The '116 Patent discloses that blocked nucleotides are examples of modified nucleotides: "A particularly useful SBS protocol exploits modified nucleotides having removable 3' blocks . . ." (Ex. 5, '116 Patent at 40:46–47.) The Element 2023 Publication states that the AVITI Systems use blocked nucleotides. "[A]vidity sequencing leverages rolling circle amplification, polymerases evolved to accommodate the avidite complex formation and a separate polymerase evolved for efficient incorporation of unlabeled and ***3' blocked nucleotides***." (Ex. 23, Element 2023 Publication at 135.) Thus, at least one of the plurality of component wells used by the AVITI Systems during sequencing contains modified nucleotides.

202. For the AVITI Systems to proceed with sequencing, the AVITI Systems next remove the reversible terminator in the modified (blocked) nucleotide (*i.e.*, the part of the modified nucleotide that prevents the subsequent nucleotide from being added to the strand) so that the next nucleotide may be added. To do so, a solution is introduced to "cleave" the reversible terminator off the end of the modified nucleotide. This solution is called a cleavage mix. Thus, at least one of the plurality of component wells used by the AVITI Systems during sequencing contains a cleavage mix.

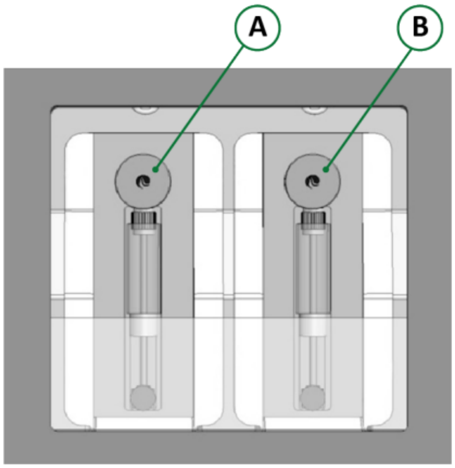
203. The AVITI Systems protect the sequencing reagents as well as the DNA fragments being sequenced from oxidation, which occurs through reactions of the sequencing reagents or DNA fragments with oxygen. Oxidation degrades the quality of the reagents and makes sequencing less accurate. Oxidizing protectants are routinely used to inhibit oxidation. In the AVITI Systems, at least one of the plurality of component wells used during sequencing contains an oxidizing protectant.

204. "a pump configured to direct the flow of fluids from the reaction component tray through the array of sipper tubes to a multi-port valve, the multi-port valve configured to selectively flow the fluids from the reaction component tray to the sample deck during DNA sequencing on the flow cell." The

AVITI Systems have a pump configured in the manner recited in Claim 1 of the ’116 Patent.

205. The AVITI System Workflow Guide states that the AVITI Systems have a pump configured to direct the flow of the fluids from the reaction component tray to the flow cell: “Each pump bay contains two pumps that control the flow of liquid. The left ***pump pulls fluid through the left lane of the flow cell and the right pump pulls fluid through the right lane***.” (Ex. 24, AVITI System Workflow Guide at 14 (emphasis added).) The pumps are illustrated in the diagram below.

Figure 6: Pumps in a pump bay



A Pump controlling the left lane of a flow cell
B Pump controlling the right lane of a flow cell

(Ex. 24, AVITI System Workflow Guide at 14; *see also* Ex. 22, AVITI24 System User Guide at 9 (same).)

206. The AVITI System Workflow Guide also states that “[p]riming prepares reagents for delivery and pumps air and reagents through a used flow cell and the fluidic [sipper] tubes, preventing contamination between runs.” (Ex. 24,

AVITI System Workflow Guide at 20; *see also* Ex. 22, AVITI24 System User Guide at 21 (same).) Hence, the AVITI Systems' pumps are configured to direct the flow of fluids from the reaction component tray through the array of sipper tubes.

207. The AVITI Systems include a multi-port valve configured to selectively flow different fluids from the sequencing cartridge (the reaction component tray) to the sample deck during DNA sequencing on the flow cell. The Element 2023 Publication states: "Reagents are delivered using a ***selector valve*** and syringe pump to perform reagent cycling." (Ex. 23, Element 2023 Publication at 134 (emphasis added).) The selector valve is the multiport valve.

208. "wherein rotation of the lead screw in a first direction moves the transport platform toward the guide plate until the array of sipper tubes is at the deposited level, wherein rotation of the lead screw in a second, opposite direction moves the transport platform away from the guide plate until the array of sipper tubes is at the withdrawn level." In the AVITI Systems, the lead screw rotates in the manner and performs the functions recited in Claim 1 of the '116 Patent.

209. The sipper tubes in the AVITI Systems move bi-directionally between a position where the sipper tubes are within the sequencing cartridge wells (the deposited level) and a position where the sipper tubes are fully withdrawn from the sequencing cartridge wells (the withdrawn level). (Ex. 24, AVITI System

Workflow Guide at 14 ("When priming starts, sippers descend into the [reagent] bay, pierce the foil seals covering the [sequencing] cartridge wells, and aspirate reagents from the bottom of each well."); Ex. 22, AVITI24 System User Guide at 9 (same).)

210. As previously alleged (*see supra* ¶¶ 188–190), the transport platform holds the array of sipper tubes. The lead screw is a device that converts the rotational motion of the drive motor into the linear (up-and-down) motion of the transport platform. When the lead screw rotates, it causes the transport platform to move either up or down, depending on the direction in which the lead screw is rotating.

211. As previously alleged (*see supra* ¶¶ 191–192), the guide plate sits under the sipper tubes in their withdrawn position. When the lead screw rotates in the direction that causes the transport platform (and attached sipper tubes) to descend, the sippers move downward toward the guide plate. When the sippers have extended into the wells of the sequencing cartridge, they have reached the deposited level. From this position, the lead screw may be rotated back in the opposite direction. This causes the transport platform and the array of sipper tubes to move upward away from the guide plate. Once the sipper tubes have completely exited the sequencing cartridge wells, they have reached the withdrawn level.

212. "wherein sipper tubes of the array of sipper tubes include distal portions that are inserted into component wells of the reaction component tray when the array of sipper tubes is at the deposited level, wherein the distal portions of the sipper tubes are completely removed from the component wells when the array of sipper tubes is at the withdrawn level." As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 94–95), Element's AVITI Systems include a transport platform holding an array of sipper tubes. As further previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶¶ 94–95), each sipper tube of the array of sipper tubes in the AVITI Systems includes a distal portion positioned to be inserted into a component well of a reaction component tray within the cavity. When the array of sipper tubes is at the deposited level, the downward end (the distal portion) of these sipper tubes is positioned within the component well. When the array of sipper tubes is at the withdrawn level, the distal portions of the sipper tubes are completely removed from the component wells of the sequencing cartridge (reaction component tray). Thus, the sipper tubes of the AVITI Systems include distal portions that are inserted into component wells of the reaction component tray when the array of sipper tubes is at the deposited level, wherein the distal portions of the sipper tubes are completely removed from the component wells when the array of sipper tubes is at the withdrawn level, as recited in Claim 1 of the '116 Patent.

213. "wherein the location sensor is configured to detect the flag and determine when the array of sipper tubes has not reached a threshold level such that the reaction component tray is not ready for removal from the cavity." The '116 Patent discloses that the location sensor detects the flag to determine the level of the array of sipper tubes: "The location sensor may detect a flag **1064** of the stage assembly **1046** to determine a level of the stage assembly **1046**. If the flag **1064** has not reached a threshold level along the Z-axis, the location sensor may communicate with the workstation **160** (or other assay system) to notify the user that the tray **1020** is not ready for removal."[5] (Ex. 5, '116 Patent at 37:55–61.) The patent further discloses that when the array of sipper tubes reaches the withdrawn level, the sequencing cartridge (the reaction component tray) "may be removed from the system cavity **1008** [] without damage to the sipper tubes **1050**" or the sequencing cartridge. (Ex. 5, '116 Patent at 37:12–16.)

214. In the AVITI Systems, the location sensor is configured as recited in Claim 1 of the '116 Patent. The location sensor detects a signal that indicates that the array of sipper tubes has not reached a threshold level such that the reaction component tray is not ready for removal from the cavity. To determine whether the sippers have reached a threshold level where the reaction

---

[5] The stage assembly includes the transport platform that holds an array of sipper tubes. Ex. 5, '116 Patent at 36:57–58, 36:66–67.

tray is ready for removal from the cavity, the location sensor detects the position of the flag.

215. As shown above, the AVITI Systems satisfy each and every limitation of Claim 1 of the ’116 Patent.

216. In violation of 35 U.S.C. § 271(a), Element has infringed the ’116 Patent by making, using, offering to sell and selling the AVITI Systems.

217. In violation of 35 U.S.C. § 271(b), Element has induced and continues to induce its customers to directly infringe, both literally and/or under the doctrine of equivalents, the ’116 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on Element’s website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element’s customers and prospective customers and/or providing technical support or other services for the products to Element’s customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the “sample deck comprising a slidable platform configured to support a fluidic device,” and loading reagents and fluids into the reagent bay

(Ex. 24, AVITI System Workflow Guide at 51–52; Ex. 22, AVITI24 System User Guide at 30–32), thereby making use of the "fluid storage system." Element knows that when Element's customers use the AVITI Systems as directed by Element, Element's customers are directly infringing the '116 Patent.

218. Element has been on notice of the infringement alleged in this Count since at least on or around the issuance of the '116 Patent on July 11, 2023. Alternatively, Element has been on notice of the '116 Patent at least since May 15, 2025, when Illumina filed and served on Element a complaint alleging that Element infringes the '116 Patent. Element has committed acts of infringement willfully and intentionally after notice of infringement.

219. Element purchased a MiSeq instrument from Illumina in February 2019. This instrument included a label noting that the patents associated with it can be accessed at www.illumina.com/patents. Element used the MiSeq instrument in its development of the AVITI Systems.

220. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT V: INFRINGEMENT OF THE '702 PATENT

221. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

222. Element has infringed at least Claims 1–11 of the ’702 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell and selling within the United States the invention claimed in the ’702 Patent.

223. Independent Claim 1 of the ’702 Patent recites:

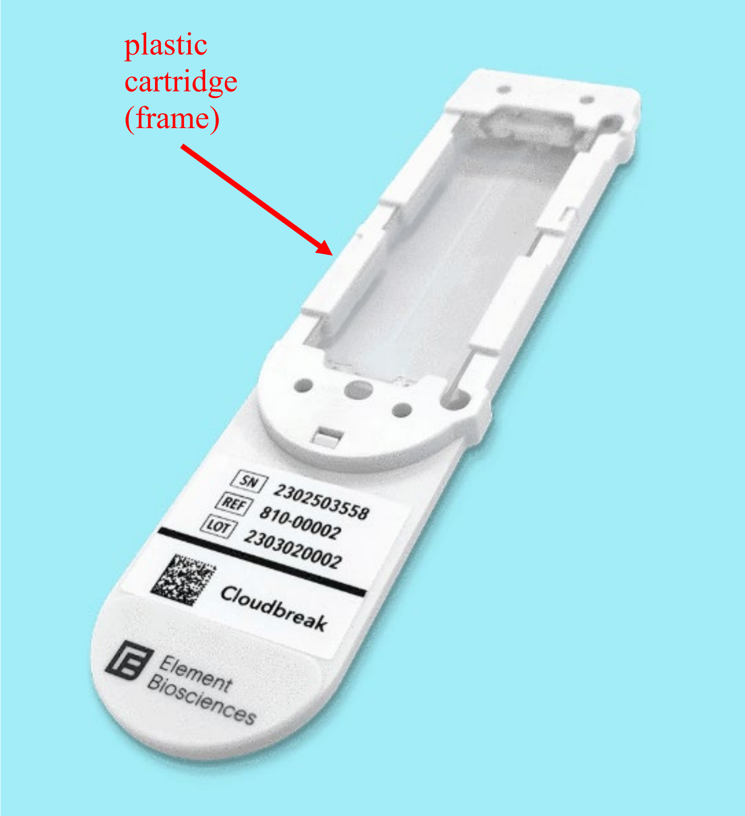
> A microfluidic cartridge comprising:
>
> a frame;
>
> a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame, the microfluidic plate comprising a first side, a first edge, and a plurality of first fluidic ports located in the first side;
>
> a support bracket positioned within the frame, wherein the support bracket floats relative to the microfluidic plate and the frame, the support bracket comprising:
>
> a plurality of seals supported by the support bracket, each seal of the plurality of seals positioned to interface with a corresponding first fluidic port of the plurality of first fluidic ports, and
>
> a plurality of alignment holes corresponding to a first plurality of indexing features located on an analysis device, the plurality of alignment holes configured to align the plurality of seals with corresponding analysis device ports located on the analysis device; and
>
> wherein the frame includes a plurality of apertures proximate the first edge of the microfluidic plate, the plurality of apertures corresponding to a second plurality of indexing features located on the analysis device, and
>
> wherein the second plurality of indexing features engage the microfluidic plate and the first plurality of indexing features engage the plurality of alignment holes to align the plurality of first fluidic ports, the plurality of seals, and the analysis device ports when the microfluidic cartridge is installed in the analysis device.

(Ex. 6, ’702 Patent at 14:6–34 & Certificate of Correction.)

224. “A microfluidic cartridge comprising.” The AVITI Systems and Element Sequencing Kits each include a microfluidic cartridge as recited in Claim 1 of the ’702 Patent. The AVITI System Workflow Guide states that “[e]ach nest holds ***one flow cell*** secured with a lid.” (Ex. 24, AVITI System Workflow Guide at 13 (emphasis added); *see also* Ex. 22, AVITI24 System User Guide at 8 (“The nest bay includes two nests, one for each side, and ***each nest holds one flow cell***.” (emphasis added)).) “The flow cell is a two-lane glass substrate encased in a plastic ***cartridge***,” which reagents enter “through inlet ports at the top of each lane” and “exit[] as waste through outlet ports at the bottom.” (Ex. 24, AVITI System Workflow Guide at 32 (emphasis added); *see also* Ex. 22, AVITI24 System User Guide at 13 (“Library and reagents enter the flow cell through inlet ports and exit as waste through outlet ports.”).) These reagents are fluids that flow through the flow cell. Thus, the flow cell and plastic cartridge in the AVITI Systems and Element Sequencing Kits are the claimed microfluidic cartridge.

225. “a frame.” The microfluidic cartridge in the AVITI Systems and Element Sequencing Kits has a frame as recited in Claim 1 of the ’702 Patent. The image below shows the Cloudbreak microfluidic cartridge sold by Element for

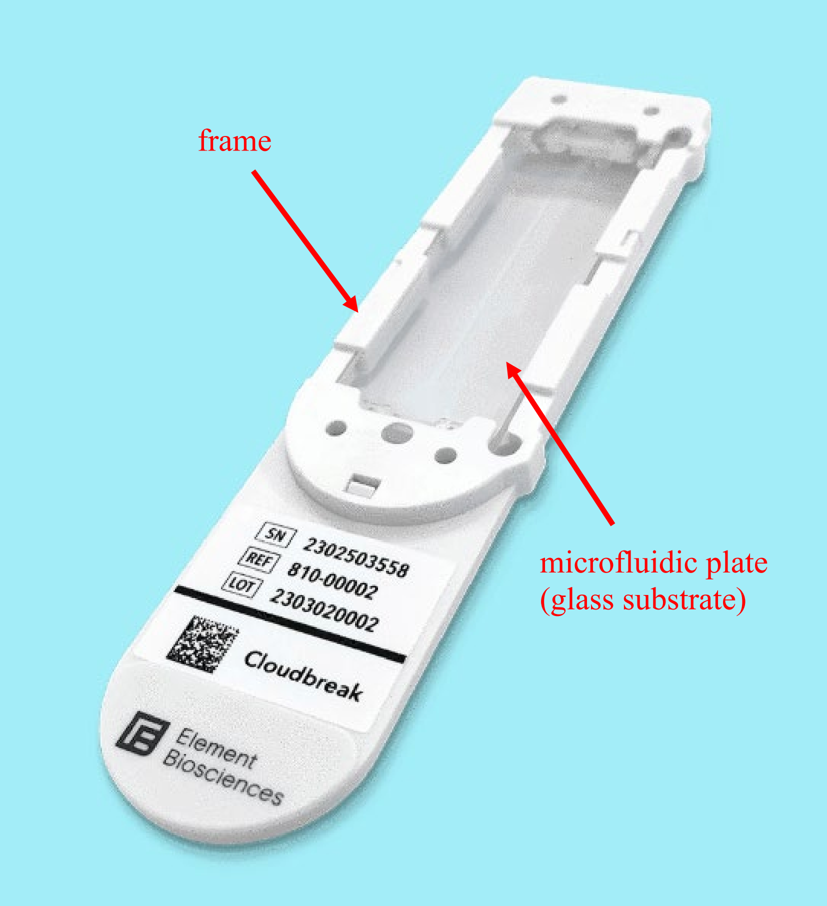
use with the AVITI Systems. The plastic cartridge in the microfluidic cartridge is a frame, as shown below.


plastic
cartridge
(frame)
SN 2302503558
REF 810-00002
LOT 2303020002
Cloudbreak
Element
Biosciences

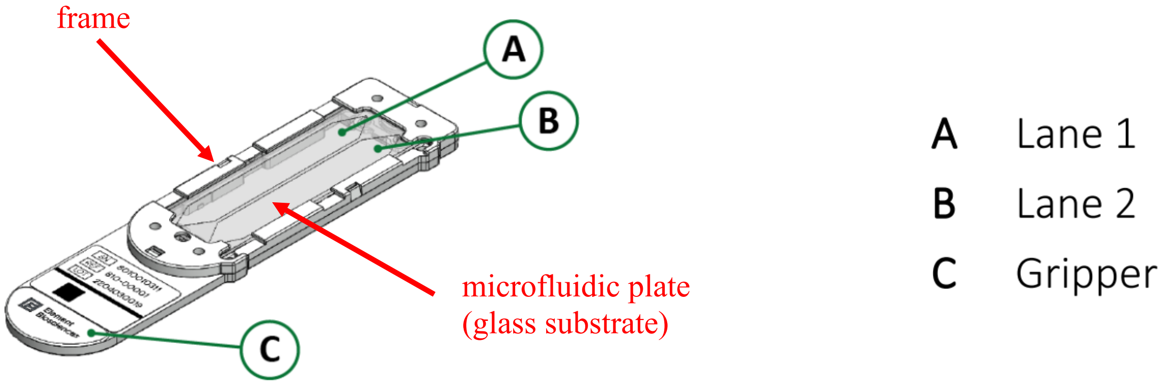
(Ex. 16, "Cloudbreak™ Sequencing Kits,"
https://www.elementbiosciences.com/products/cloudbreak (annotated).)

226. "a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame." The microfluidic cartridge in the AVITI Systems and Element Sequencing Kits has a microfluidic plate positioned within the frame as recited in Claim 1 of the '702 Patent. The microfluidic cartridge used in the AVITI Systems and Element Sequencing Kits includes "a two-lane glass substrate encased in a plastic cartridge," and fluids pass through the two lanes within the substrate. (Ex. 9, AVITI System User Guide at 13; Ex. 22,

AVITI24 System User Guide at 13 (same).) The glass substrate, shown in the images below, is the microfluidic plate.

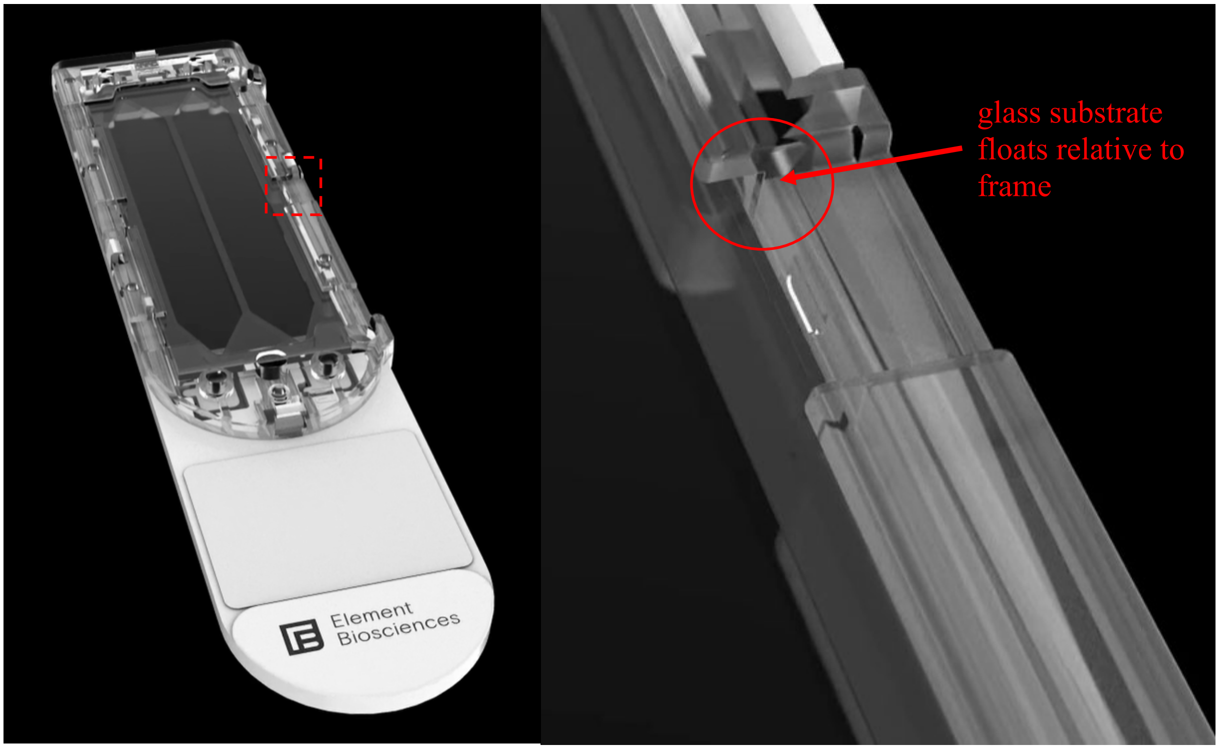

frame
microfluidic plate
(glass substrate)
SN 2302503558
REF 810-00002
LOT 2303020002
Cloudbreak
Element
Biosciences

(Ex. 16, "Cloudbreak™ Sequencing Kits," https://www.elementbiosciences.com/products/cloudbreak (annotated).)

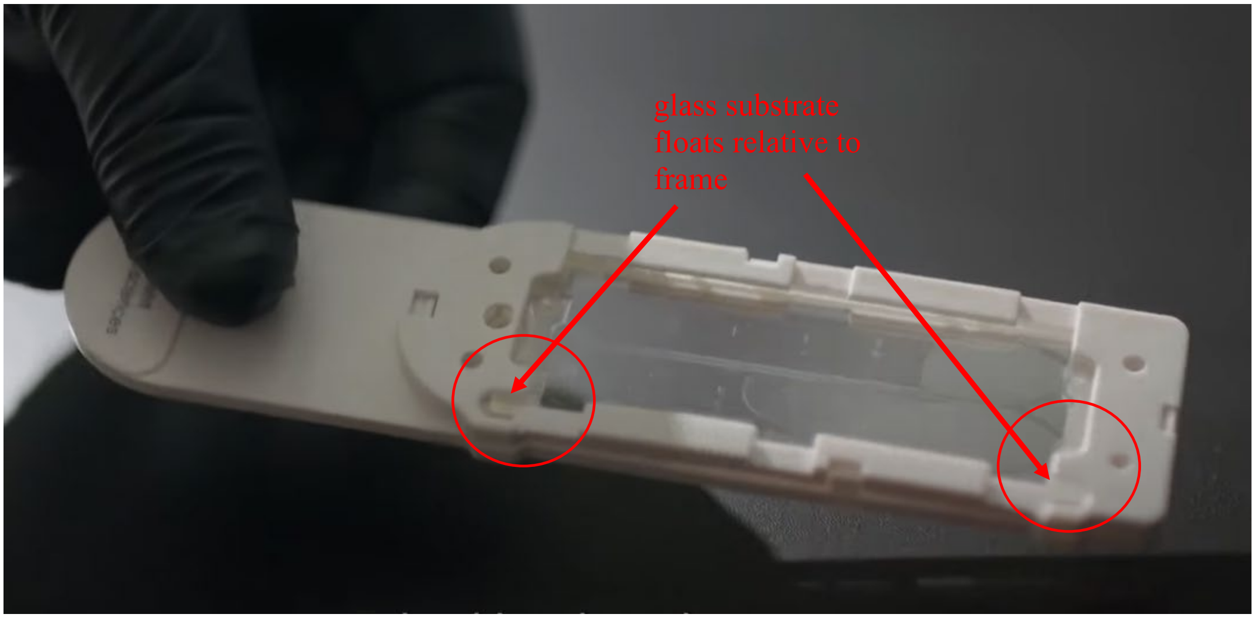

frame
A
B
C
microfluidic plate
(glass substrate)
A Lane 1
B Lane 2
C Gripper

(Ex. 22, AVITI24 System User Guide at 13 (green annotations in original, red annotations added).)

227. The below image of the microfluidic cartridge in the AVITI Systems and Element Sequencing Kits shows that the glass substrate (the microfluidic plate) floats relative to the frame.

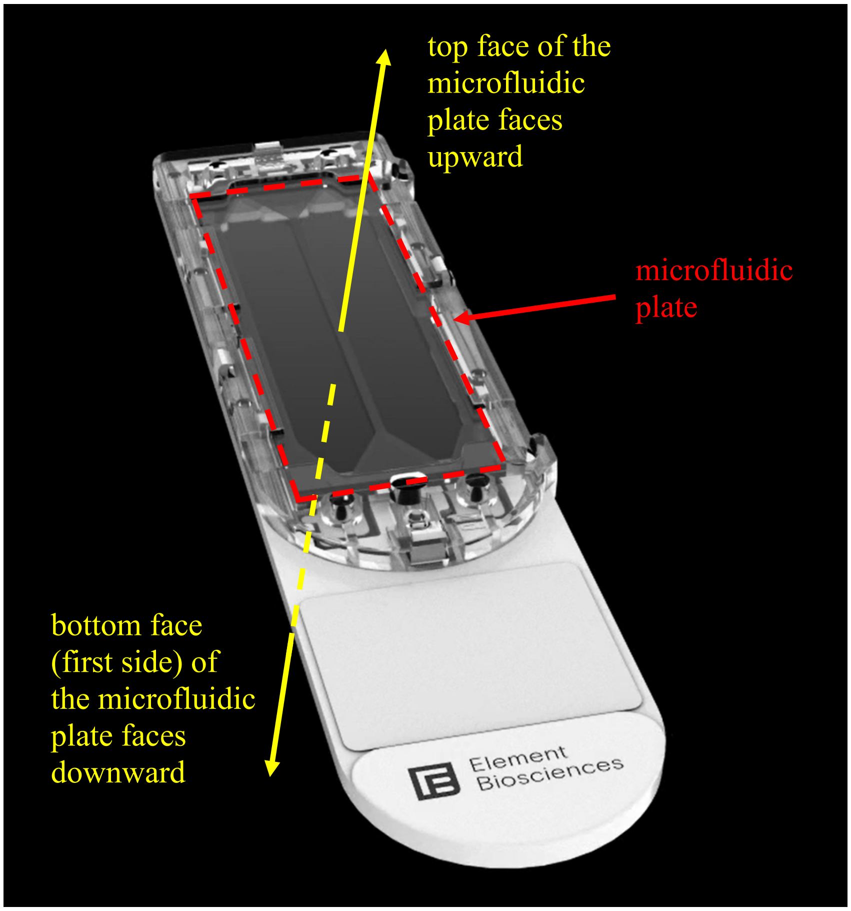

Element Biosciences
glass substrate floats relative to frame

(Ex. 30, "Element Biosciences Cloudbreak Freestyle Sequencing Kits," https://player.vimeo.com/video/927684676 at 0:05 (annotated).)


glass substrate floats relative to frame

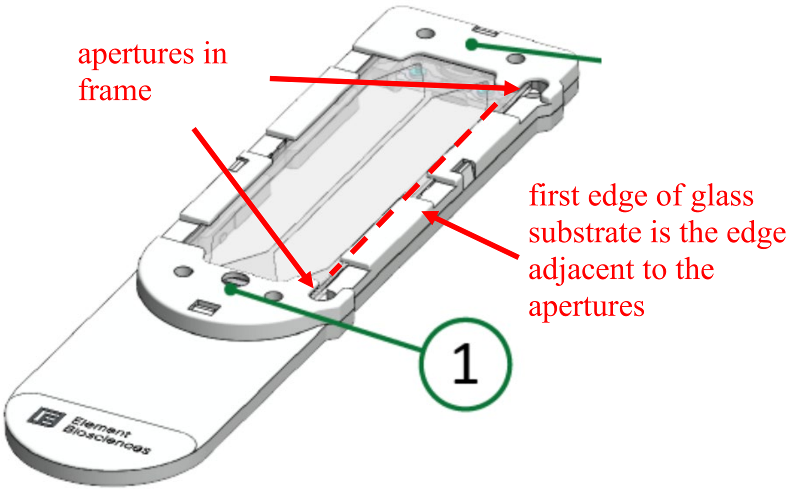
(Ex. 31, "AVITI24™ at the University of Minnesota Genomics Center," https://www.youtube.com/watch?v=o6roQOvAlXE at 0:23 (Feb. 25, 2025) (annotated).)

228. "the microfluidic plate comprising a first side, a first edge, and a plurality of first fluidic ports located in the first side." The microfluidic plate in the AVITI Systems and Element Sequencing Kits comprises a first side, a first edge and a plurality of first fluidic ports located in the first side as recited in Claim 1 of the '702 Patent. The glass substrate (the microfluidic plate) includes a first side—the bottom face of the glass substrate. As shown below, the bottom face has four edges, which follow the dotted red lines.


top face of the microfluidic plate faces upward
microfluidic plate
bottom face (first side) of the microfluidic plate faces downward
Element Biosciences

(Ex. 30, "Element Biosciences Cloudbreak Freestyle Sequencing Kits," https://player.vimeo.com/video/927684676 at 0:05 (annotated).)

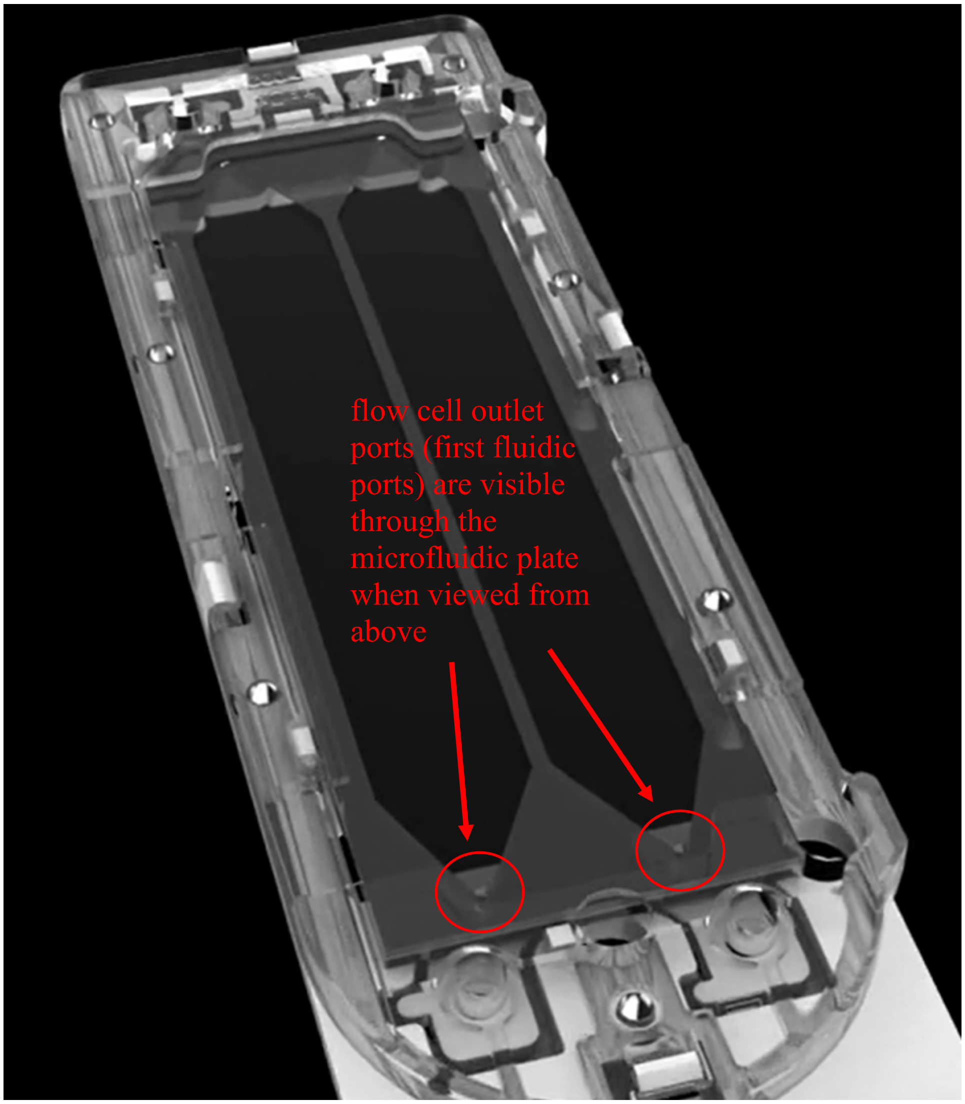
229. The first side (bottom face) has a first edge—the edge of the glass substrate that is on the right in the image below. As shown below, the ends of the first edge are marked by two apertures in the frame.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotations in original, red annotations added).)

230. The bottom face (the first side) of the glass substrate (the microfluidic plate) contains a plurality of first fluidic ports. In the AVITI Systems, "reagents enter the flow cell through inlet ports at the top of each lane, saturating the surface and exiting as waste through outlet ports at the bottom." (Ex. 24, AVITI System Workflow Guide at 32; Ex. 22, AVITI24 System User Guide at 13 ("[R]eagents enter the flow cell through inlet ports and exit as waste through outlet ports.").) As shown in the image below, these flow cell outlet ports (the first

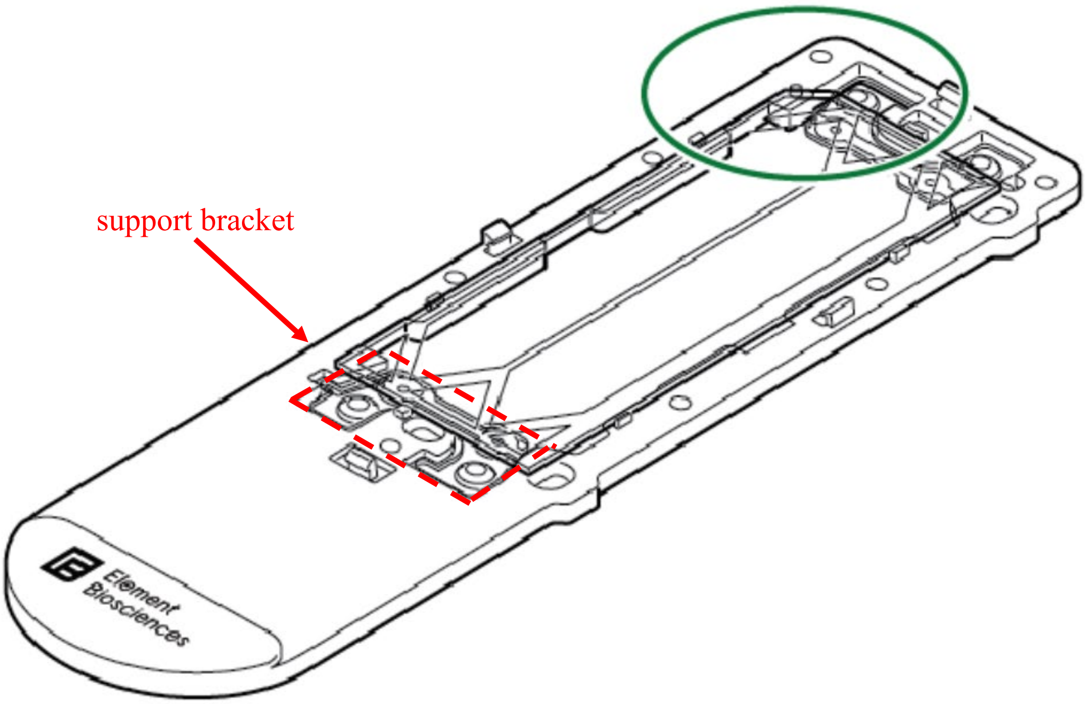
fluidic ports) are located on the bottom face (the first side) of the glass substrate (the microfluidic plate).


flow cell outlet
ports (first fluidic
ports) are visible
through the
microfluidic plate
when viewed from
above

(Ex. 30, "Element Biosciences Cloudbreak Freestyle Sequencing Kits," https://player.vimeo.com/video/927684676 at 0:06 (annotated).)

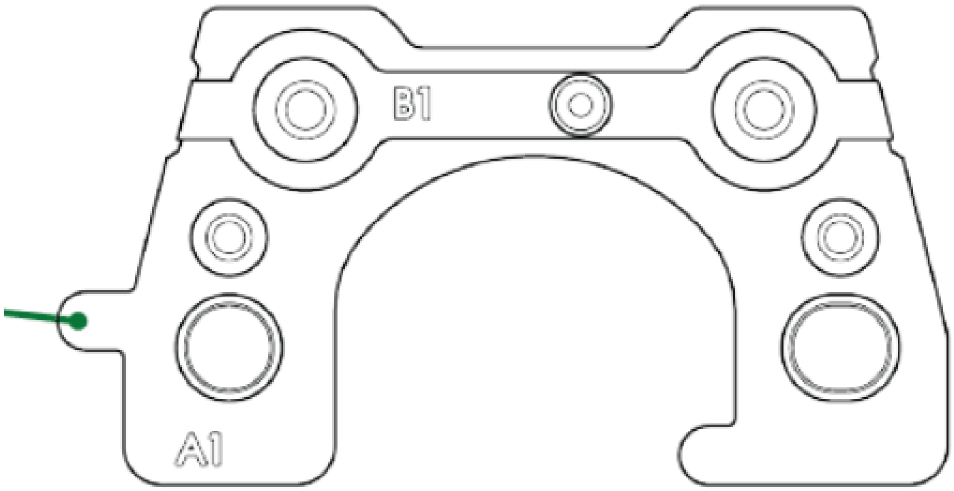
231. "a support bracket positioned within the frame, wherein the support bracket floats relative to the microfluidic plate and the frame, the support bracket comprising." The microfluidic cartridge in the AVITI Systems and Element Sequencing Kits has a support bracket positioned within the frame as

recited in Claim 1 of the '702 Patent. The image below shows a partially assembled microfluidic cartridge for use with the AVITI Systems. Within the frame is a support bracket. (Ex. 20, Teton CytoProfiling User Guide at 25 (referring to the support bracket as a gasket).)



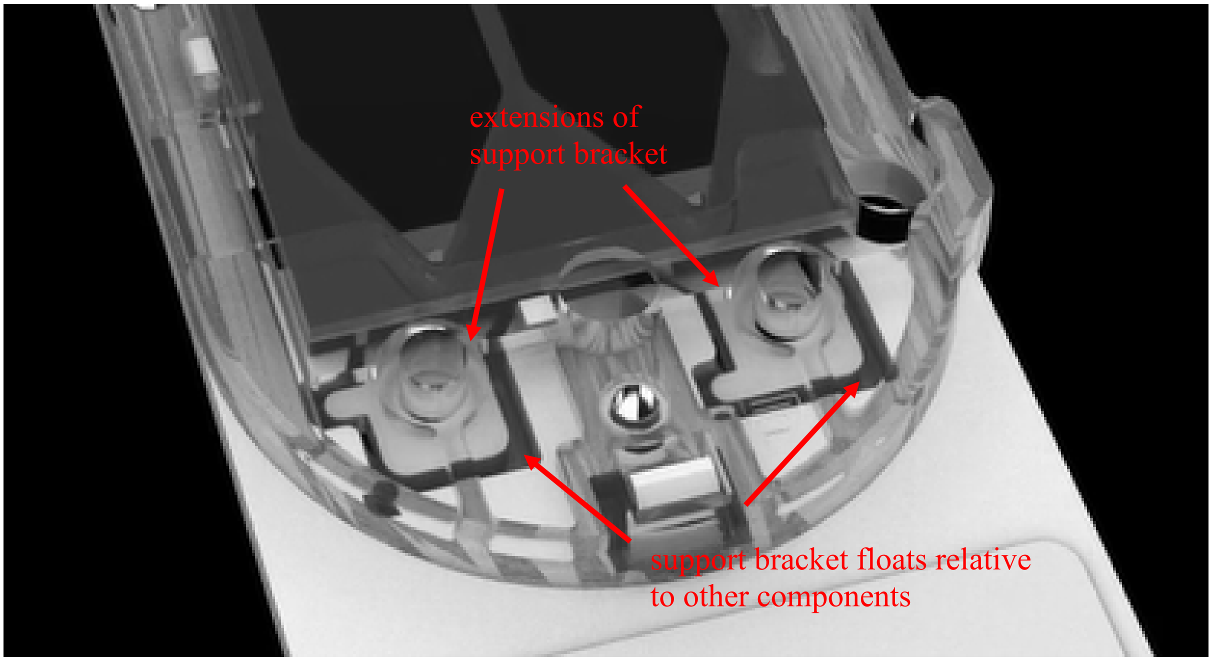
(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

232. The below image shows the support bracket.



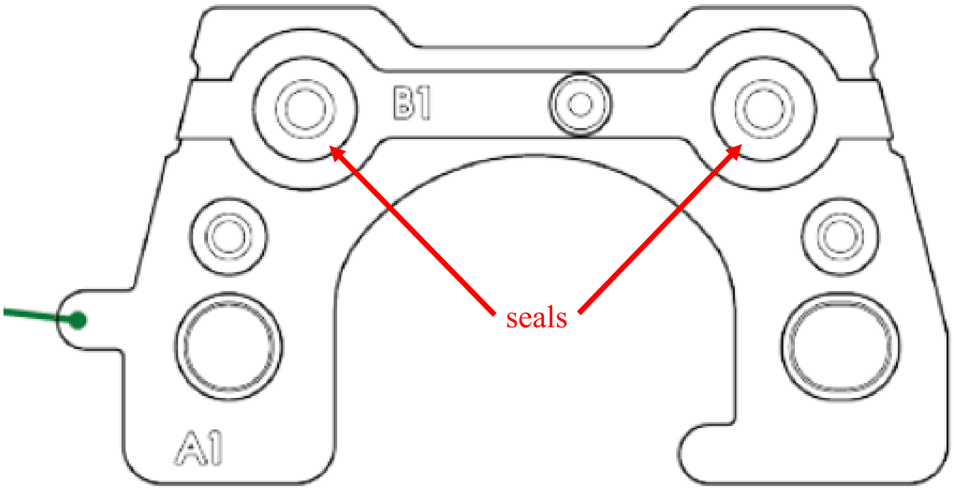
(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original).)

233. In the microfluidic cartridge of the AVITI Systems and Element Sequencing Kits, the frame includes a recess that is sized to receive the support bracket such that the bracket can float relative to the other components. As shown in the below image, when the support bracket is in place, there are gaps between the support bracket and the walls of the recess, which allows the support bracket to float relative to both the glass substrate (the microfluidic plate) and the plastic cartridge (the frame).


extensions of
support bracket
support bracket floats relative
to other components

(Ex. 30, "Element Biosciences Cloudbreak Freestyle Sequencing Kits," https://player.vimeo.com/video/927684676 at 0:06 (annotated).)

234. "a plurality of seals supported by the support bracket." The microfluidic cartridge in the AVITI Systems and Element Sequencing Kits has a plurality of seals supported by the support bracket as recited in Claim 1 of the '702 Patent. As shown below, the support bracket includes a compressible material (marked as "B1") having two seals (that is, a plurality of seals).



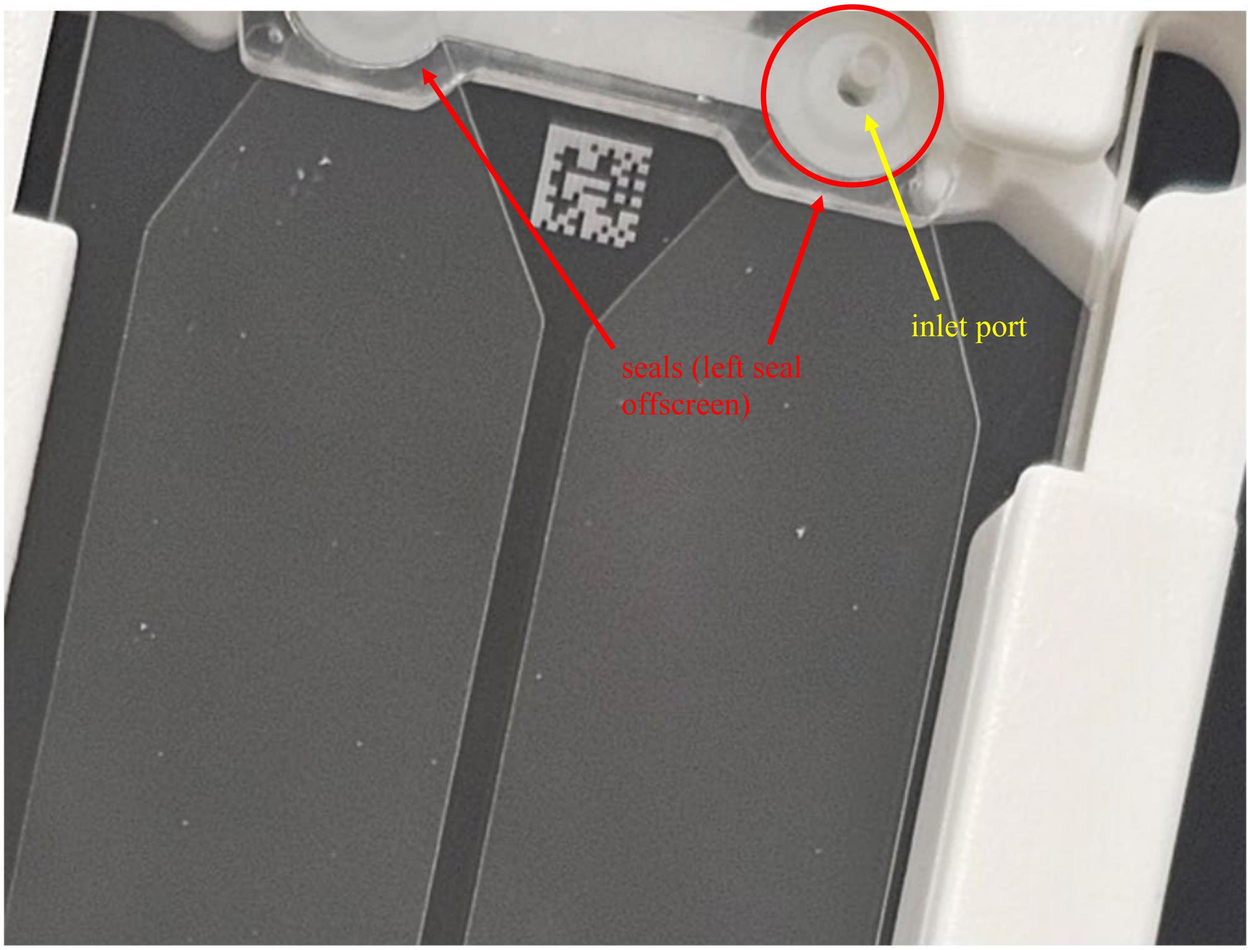
(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

235. "each seal of the plurality of seals positioned to interface with a corresponding first fluidic port of the plurality of first fluidic ports." Each seal of the plurality of seals in the AVITI Systems and Element Sequencing Kits is positioned to interface with a corresponding fluidic port as recited in Claim 1 of the '702 Patent.

236. The flow cell of the AVITI Systems and the Element Sequencing Kits has two flow cell inlet ports in addition to the flow cell outlet ports (the plurality of first fluidic ports) on the glass substrate (the microfluidic plate). Identical support brackets, each supporting a plurality of seals, interface with both the flow cell inlet ports and the flow cell outlet ports (the plurality of first fluidic ports). (Ex. 20, Teton CytoProfiling User Guide at 6 ("The Teton flow cell assembly kit contains an adhesive slide, ***two flow cell gaskets [i.e., support brackets]***, and the top and bottom cartridge parts." (emphasis added)).)

237. The two seals sit directly over the ends of the two flow lanes in the glass substrate (the microfluidic plate), where the flow cell outlet ports of the glass substrate are positioned. Thus, when the support bracket is in place, each seal is positioned to interface with one of the flow cell outlet ports (a corresponding first fluidic port of the plurality of first fluidic ports) of the glass substrate. The image below shows the flow cell ***inlet*** ports of the flow cell in the

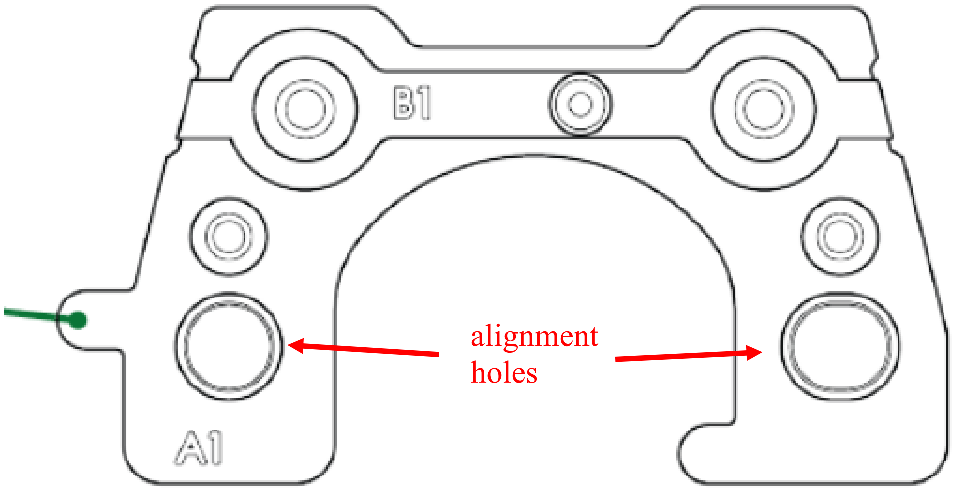
AVITI Systems and Element Sequencing Kits. The relationship between the flow cell ***inlet*** ports and the seals on the depicted support bracket is identical to the relationship between the flow cell ***outlet*** ports (the first plurality of fluidic ports) and the seals on the other support bracket.



(Ex. 15, Cloudbreak Sequencing User Guide at 28 (annotated).)

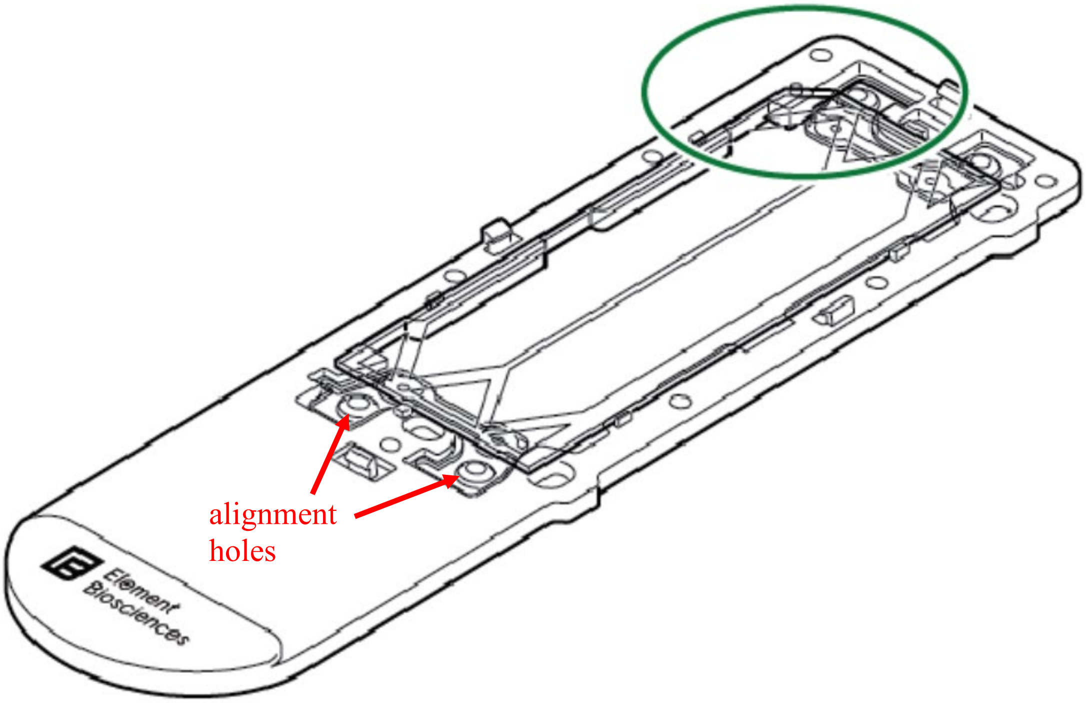
238. "a plurality of alignment holes corresponding to a first plurality of indexing features located on an analysis device." The support bracket of the microfluidic cartridge in the AVITI Systems and Element Sequencing Kits has a

plurality of alignment holes as recited in Claim 1 of the ’702 Patent. The support bracket, shown in the image below, includes two holes used to align the seals.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

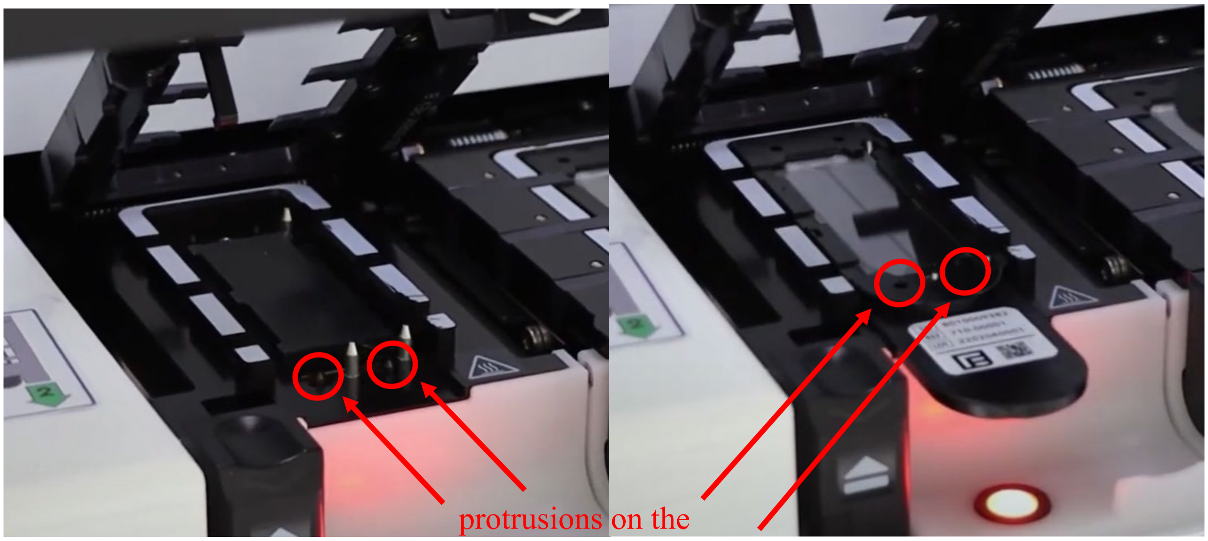
239. The image below depicts the position of the alignment holes when the support bracket is in its place in the microfluidic cartridge. The plurality of alignment holes includes these two holes.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

240. The sequencing instrument in the AVITI Systems is an analysis device. The AVITI is a "next-generation sequencing (NGS) system," (Ex. 9, AVITI System User Guide at 6), and the AVITI24 is a "multidimensional genomics instrument." (Ex. 22, AVITI24 System User Guide at 6.) Both have "[o]nboard primary ***analysis***" software which "calls bases, assigns quality scores (Q scores), and generates run metrics." (Ex. 9, AVITI System User Guide at 22 (emphasis added); Ex. 22, AVITI24 System User Guide at 24 (same).) As shown below, when the microfluidic cartridge is installed in the AVITI Systems, protrusions extend into the two alignment holes in the support bracket (the plurality of alignment holes) to position the seals. These protrusions on the nest of

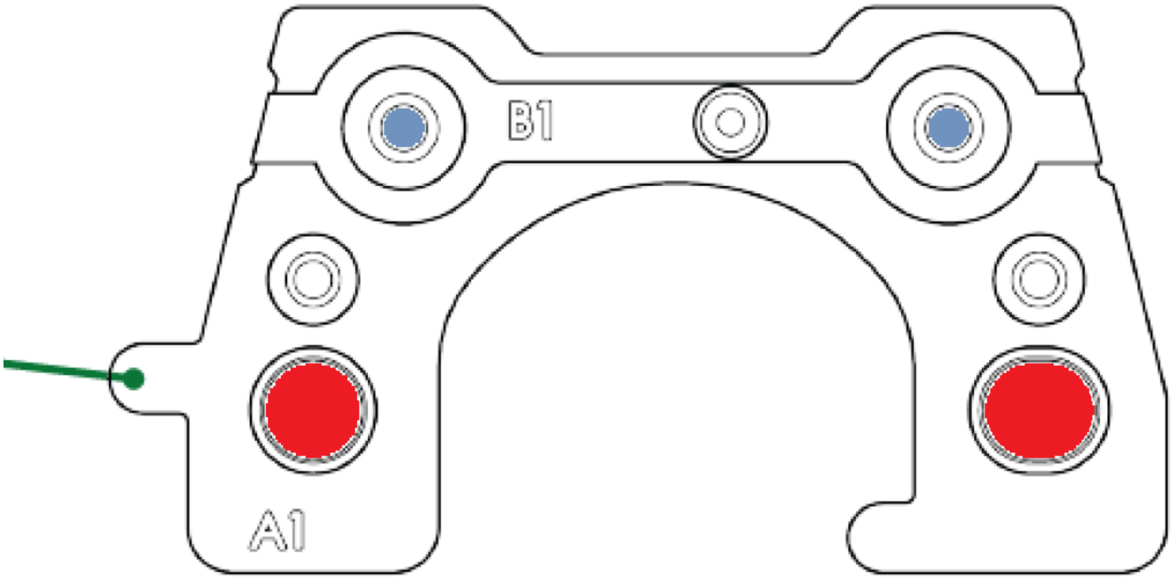
the AVITI Systems are a first plurality of indexing features located on the sequencing instrument (the analysis device). Thus, the plurality of alignment holes in the support bracket corresponds to the first plurality of indexing features on an analysis device.


protrusions on the sequencing instrument extend into the alignment holes in the support bracket

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

241. "the plurality of alignment holes configured to align the plurality of seals with corresponding analysis device ports located on the analysis device." The plurality of alignment holes in the AVITI Systems and Element Sequencing Kits is configured to align the plurality of seals with corresponding analysis device ports as recited in Claim 1 of the '702 Patent.

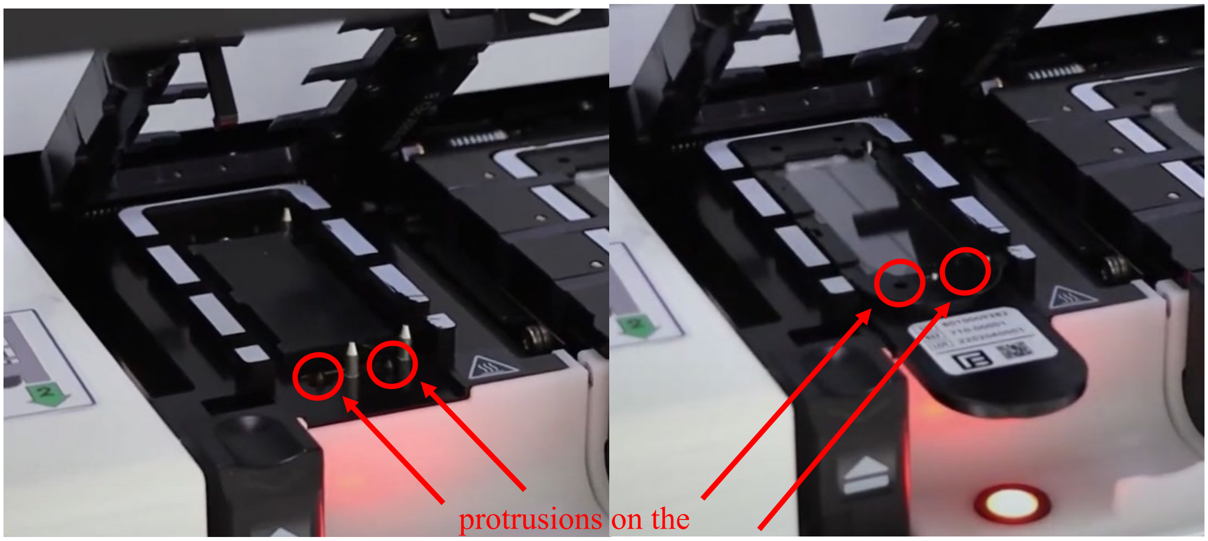
242. The below image of the bracket shows the two holes in the bracket (the plurality of alignment holes) colored in **red** and the two seal holes colored in **blue**.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red and blue coloring added).)

243. In the AVITI Systems, "[l]ibrary and reagents enter the flow cell through inlet ports and exit as waste through outlet ports." (Ex. 9, AVITI System User Guide at 13; Ex. 22, AVITI24 System User Guide at 13 (same).) In the AVITI Systems, when the protrusions on the sequencing instrument (the first plurality of indexing features) are inserted into the alignment holes in the support bracket (the plurality of alignment holes), as shown in the image below, the support bracket is positioned such that the seals on the support bracket (the plurality of seals) that interface with the outlet ports of the flow cells align with the

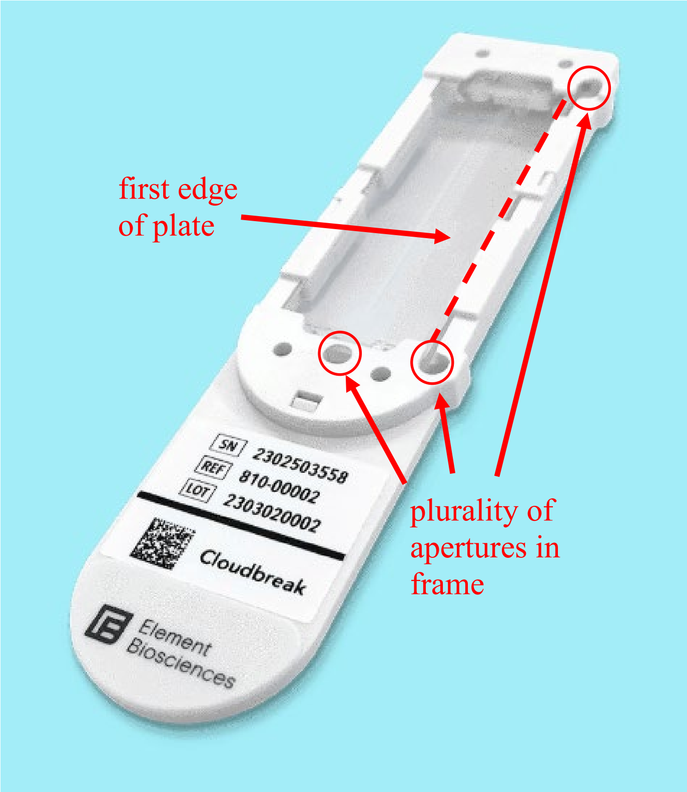
AVITI Systems ports (the analysis device ports) on the sequencer (the analysis device). Thus, the alignment holes in the support bracket are configured to align the plurality of seals in the support bracket with corresponding analysis device ports located on the sequencing instrument (the analysis device).


protrusions on the sequencing instrument extend into the alignment holes in the support bracket

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

244. "wherein the frame includes a plurality of apertures proximate the first edge of the microfluidic plate." The frame of the microfluidic cartridge in the AVITI Systems and Element Sequencing Kits includes a plurality of apertures proximate the first edge of the microfluidic plate as recited in Claim 1 of the '702 Patent.

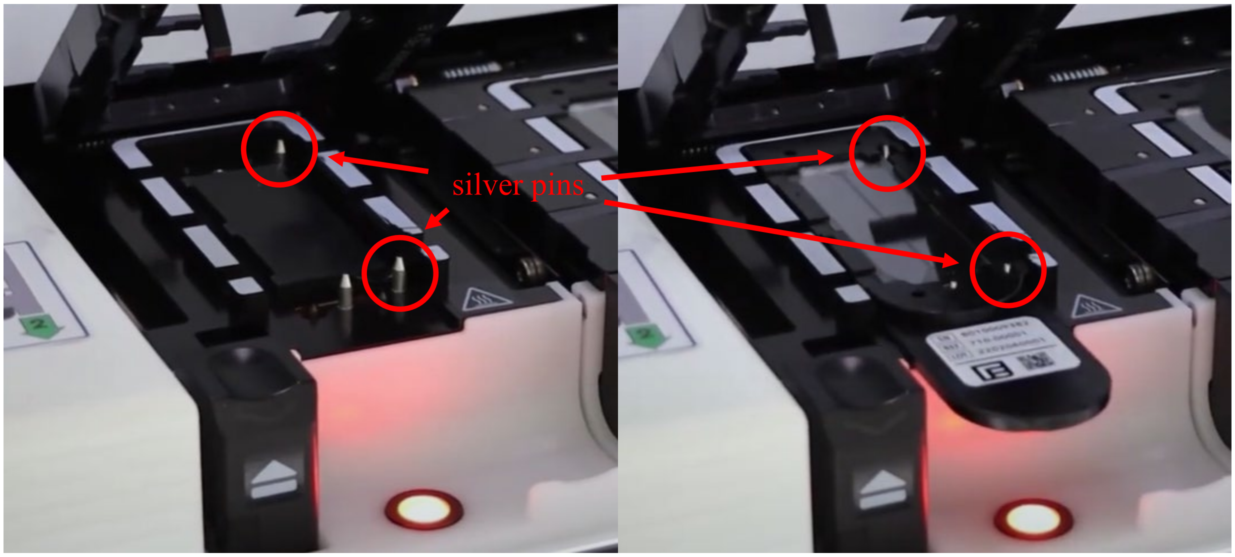
245. As shown in the image below, the frame includes three holes, or apertures. Two of the apertures are proximate to the edge with ends marked by two of the apertures (the first edge) of the glass substrate (the microfluidic plate), which is the rightward edge in the image below.


first edge
of plate
plurality of
apertures in
frame
SN 2302503558
REF 810-00002
LOT 2303020002
Cloudbreak
Element
Biosciences

(Ex. 16, "Cloudbreak™ Sequencing Kits," https://www.elementbiosciences.com/products/cloudbreak (annotated).)

246. "the plurality of apertures corresponding to a second plurality of indexing features located on the analysis device." The two holes (the plurality of apertures) in the frame correspond to the indexing features located on the sequencing instrument (the analysis device) as recited in Claim 1 of the '702 Patent. In the AVITI Systems and Element Sequencing Kits, "three silver pins on the loading area fit into three ***corresponding*** holes on the flow cell cartridge [*i.e.*,

the frame].” (Ex. 9, AVITI System User Guide at 8 (emphasis added); Ex. 22, AVITI24 System User Guide at 8 (same).) As shown in the image below, when the microfluidic cartridge is installed in the AVITI Systems, two of the three silver pins extend through the two apertures proximate to the first edge of the glass substrate (the microfluidic plate) to position the microfluidic cartridge on the sequencing instrument (the analysis device). Thus, the plurality of apertures proximate the first edge corresponds to these two silver pins, which are a second plurality of indexing features located on the sequencing instrument (the analysis device).

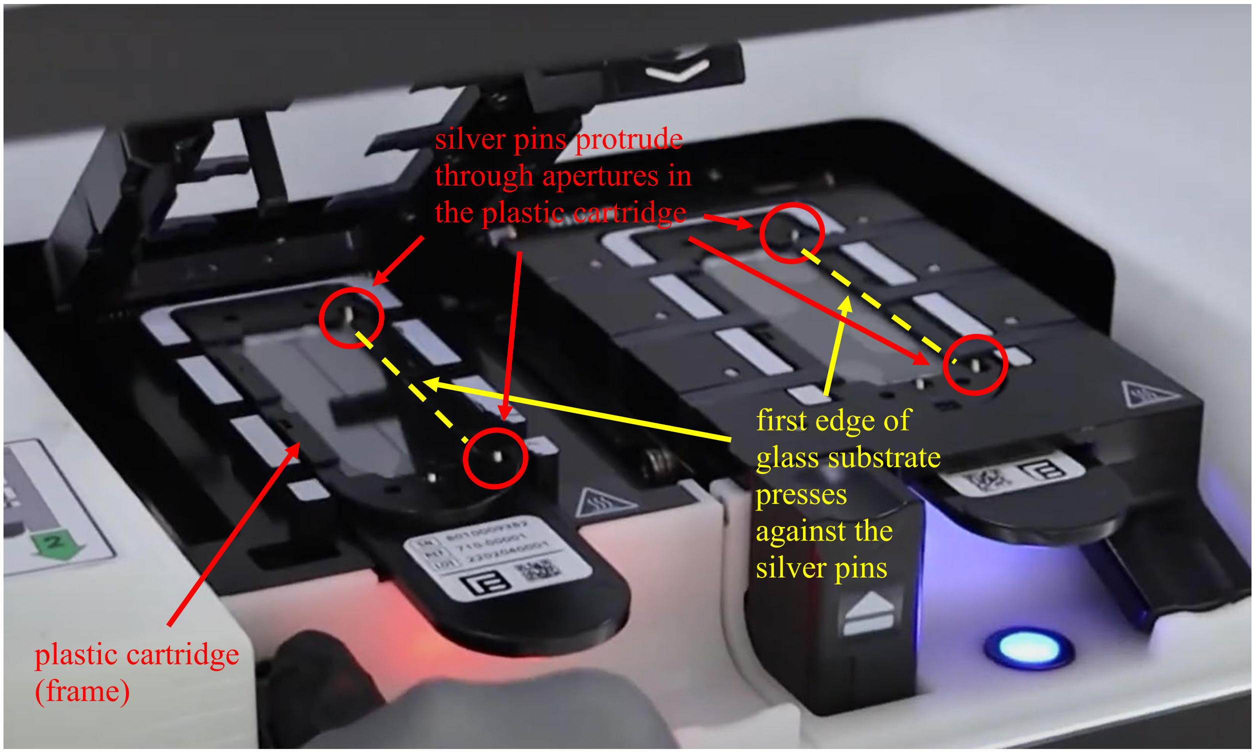


(Ex. 26, “Element AVITI™ System - Instrument Demonstration,” https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

247. “wherein the second plurality of indexing features engage the microfluidic plate and.” The second plurality of indexing features in the AVITI Systems engage the microfluidic plate, as recited in Claim 1 of the ’702 Patent.

This clause is part of the wherein clause: "***wherein the second plurality of indexing features engage the microfluidic plate and*** the first plurality of indexing features engage the plurality of alignment holes to align the plurality of first fluidic ports, the plurality of seals, and the analysis device ports when the microfluidic cartridge is installed in the analysis device."

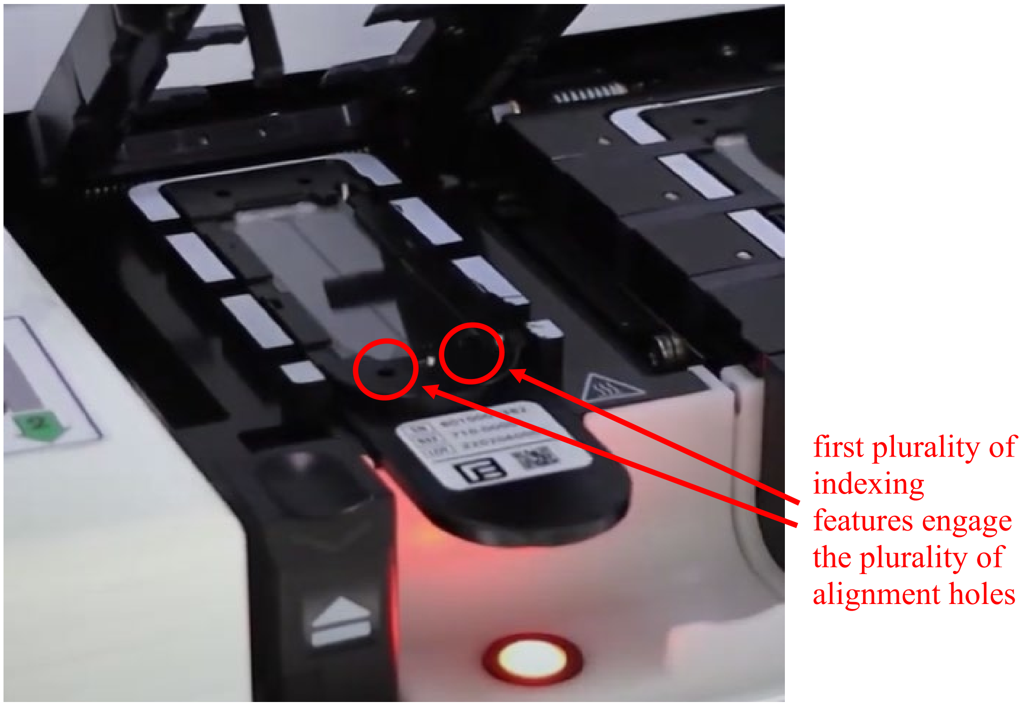
248. As shown in the image below, the apertures in the plastic cartridge (the frame) are configured such that the two silver pins (the second plurality of indexing features) engage the first edge of the glass substrate (the microfluidic plate) to align the first fluidic ports with the plurality of seals when the microfluidic device is installed in the AVITI Systems.


silver pins protrude through apertures in the plastic cartridge
first edge of glass substrate presses against the silver pins
plastic cartridge (frame)

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 4:56 (July 21, 2022) (annotated).)

249. "the first plurality of indexing features engage the plurality of alignment holes." The first plurality of indexing features engage the plurality of alignment holes, as recited in Claim 1 of the '702 Patent. This clause is part of the wherein clause: "wherein the second plurality of indexing features engage the microfluidic plate and ***the first plurality of indexing features engage the plurality of alignment holes*** to align the plurality of first fluidic ports, the plurality of seals, and the analysis device ports when the microfluidic cartridge is installed in the analysis device."

250. As shown in the image below, the two protrusions on the sequencing instrument (the first plurality of indexing features) engage the holes in the support bracket (the plurality of alignment holes in the support bracket) to align the plurality of seals with the analysis device ports when the flow cell and plastic cartridge (together, the microfluidic cartridge) are installed in the sequencing instrument (the analysis device).



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

251. "to align the plurality of first fluidic ports, the plurality of seals, and the analysis device ports when the microfluidic cartridge is installed in the analysis device." In the AVITI Systems, the indexing features and the alignment holes align the plurality of first fluidic ports, the plurality of seals and the analysis device ports when the microfluidic cartridge is installed in the analysis device, as recited in Claim 1 of the '702 Patent. This clause is part of the wherein clause: "wherein the second plurality of indexing features engage the microfluidic plate and the first plurality of indexing features engage the plurality of alignment holes ***to align the plurality of first fluidic ports, the plurality of seals, and the analysis device ports when the microfluidic cartridge is installed in the analysis device***."

252. In the AVITI Systems, "reagents enter the flow cell [*i.e.*, the microfluidic cartridge] through inlet ports and exit as waste through outlet ports [*i.e.*, the first fluidic ports]." (Ex. 9, AVITI System User Guide at 13; Ex. 22, AVITI24 System User Guide at 13 (same).) As noted above, the protrusions (the first plurality of indexing features) that fit into the holes in the support bracket (the alignment holes) align the seals on the support bracket (the plurality of seals) with the sequencing instrument ports (the analysis device ports), and the silver pins (the second plurality of indexing features) that fit into the apertures in the frame (the plurality of apertures) align the flow cell outlet ports (the first fluidic ports) with the seals on the support bracket (the plurality of seals). Thus, the two pluralities of indexing features cooperate to align the flow cell outlet ports (the plurality of first fluidic ports), the ports on the sequencing device (the analysis device ports), and the seals on the support bracket that interface between them (the plurality of seals) when the flow cell and plastic cartridge (together, the microfluidic cartridge) are installed in the sequencing instrument (the analysis device).

253. As shown above, the Element Sequencing Kits and the AVITI Systems that make use of the Element Sequencing Kits satisfy each and every limitation of Claim 1 of the '702 Patent. The Element Sequencing Kits and the AVITI Systems that make use of the Element Sequencing Kits also satisfy each and every limitation of at least Claims 2–11.

254. In violation of 35 U.S.C. § 271(a), Element has infringed the ’702 Patent by making, using, offering to sell and selling the Element Sequencing Kits and the AVITI Systems.

255. In violation of 35 U.S.C. § 271(b), Element has induced and continues to induce its customers to directly infringe, both literally and/or under the doctrine of equivalents, the ’702 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on Element’s website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element’s customers and prospective customers and/or providing technical support or other services for the products to Element’s customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the “microfluidic cartridge,” and monitoring sequencing metrics (Ex. 24, AVITI System Workflow Guide at 53–54; Ex. 22, AVITI24 System User Guide at 24), thereby making use of the “analysis device.” The user guides for the Element Sequencing Kits similarly direct the user perform infringing uses of the Element Sequencing Kits, including loading a flow cell into the nest (Ex. 15,

Cloudbreak Sequencing User Guide at 18; Ex. 18, Trinity Sequencing User Guide at 11–12; Ex. 20, Teton CytoProfiling User Guide at 24–25), again making use of the "microfluidic cartridge." Element knows that when Element's customers use the Element Sequencing Kits and the AVITI Systems that make use of the Element Sequencing Kits as directed by Element, Element's customers are directly infringing the '702 Patent.

256. Element has been on notice of the infringement alleged in this Count since at least on or around the publication of U.S. Patent Application No. 18/827,174 (Publication No. US 2024/0424500)—from which the '702 Patent issued—on December 26, 2024. Alternatively, Element has been on notice of the '702 Patent at least since May 15, 2025, when Illumina filed and served on Element a complaint alleging that Element infringes the '702 Patent.

257. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT VI: INFRINGEMENT OF THE '028 PATENT

258. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

259. Element has infringed at least Claims 1–8 of the '028 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell and selling within the United States the inventions claimed in the '028 Patent.

260. Independent Claim 1 of the ’028 Patent recites:

> A chemical or biological analysis system comprising:
>
> a microfluidic cartridge that includes:
>
> a frame;
>
> a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame, the microfluidic plate comprising a first side, a first edge, and a plurality of first fluidic ports located in the first side; and
>
> a bracket positioned within the frame, wherein the bracket floats relative to the microfluidic plate and the frame, the bracket comprising a gasket and a plurality of alignment holes, wherein the frame includes a plurality of apertures proximate the first edge of the microfluidic plate; and
>
> a sequencer with a receiver configured to receive the microfluidic cartridge, the receiver including:
>
> a chuck;
>
> a plurality of analysis device ports;
>
> a first plurality of indexing features corresponding to the plurality of alignment holes; and
>
> a second plurality of indexing features corresponding to the plurality of apertures, wherein:
>
> the first plurality of indexing features and the plurality of alignment holes are configured to align the plurality of analysis device ports and the gasket, and
>
> the second plurality of indexing features are configured to engage the microfluidic plate to align the plurality of first fluidic ports and the gasket.

(Ex. 7, ’028 Patent at 14:6–34.)

261. "A chemical or biological analysis system comprising." The '028 Patent discloses that DNA sequencers are a type of chemical or biological analysis system. (Ex. 7, '028 Patent at 1:28–31 ("Sequencers, e.g., genome sequencers such as DNA sequencers or RNA sequencers, and other biological or chemical analysis systems may sometimes utilize microfluidic flow cells.").) As previously alleged in regard to Claim 1 of the '116 Patent (*see supra* ¶¶ 173–175), the AVITI Systems are DNA sequencing instruments—a type of chemical or biological analysis system that analyzes DNA molecules. (*See also* Ex. 24, AVITI System Workflow Guide at 6 ("The Element AVITI System is a mid-throughput next-generation sequencing (NGS) system that amplifies and sequences DNA libraries."); Ex. 22, AVITI24 System User Guide at 6 ("The AVITI24 System measures a diverse array of molecular features for deep multiomic profiling of RNA, protein, and morphology in a single sample in 24 hours.").) The AVITI Systems are therefore the chemical or biological analysis system recited in Claim 1 of the '028 Patent.

262. "a microfluidic cartridge that includes." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶ 224), the AVITI Systems include a flow cell and a plastic cartridge. Together, the flow cell and plastic cartridge comprise the microfluidic cartridge recited in Claim 1 of the '028 Patent.

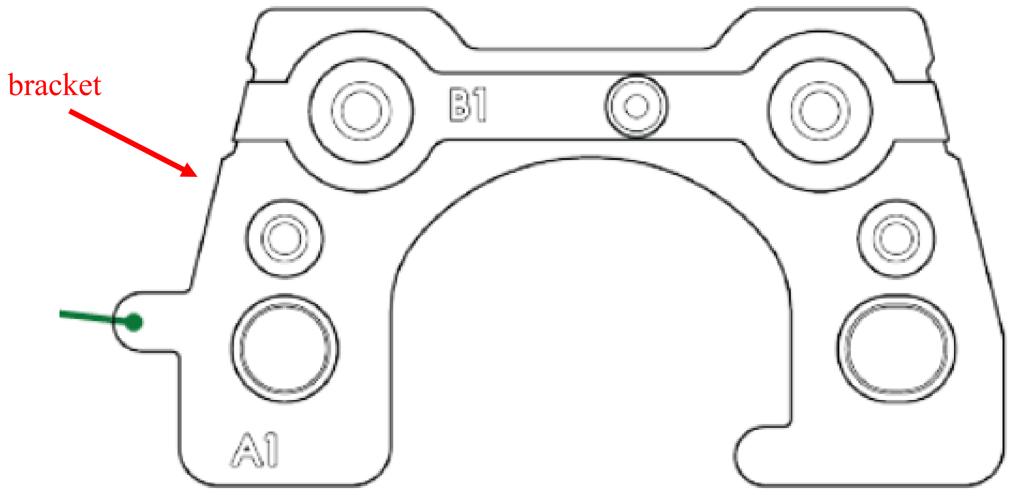
263. "a frame." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶ 225), the microfluidic cartridge in the AVITI Systems includes a plastic cartridge. The plastic cartridge of the microfluidic cartridge is the frame recited in Claim 1 of the '028 Patent.

264. "a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 226–227), the microfluidic cartridge in the AVITI Systems has a glass substrate positioned within the frame that floats relative to the frame. This glass substrate is the floating microfluidic plate recited in Claim 1 of the '028 Patent.

265. "the microfluidic plate comprising a first side, a first edge, and a plurality of first fluidic ports located in the first side; and." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 228–230), the microfluidic plate in the AVITI Systems has a first side, a first edge and a plurality of first fluidic ports located in the first side. In the AVITI Systems, the first side of the two-lane glass substrate (the microfluidic plate) is the bottom face, the first edge of the glass substrate is the edge on the right side when the microfluidic cartridge is facing up, and the flow cell outlet ports that are located on the bottom face of the glass substrate are the plurality of first fluidic ports located on the first side. These

are the first side, first edge and ports of the microfluidic plate recited in Claim 1 of the '028 Patent.

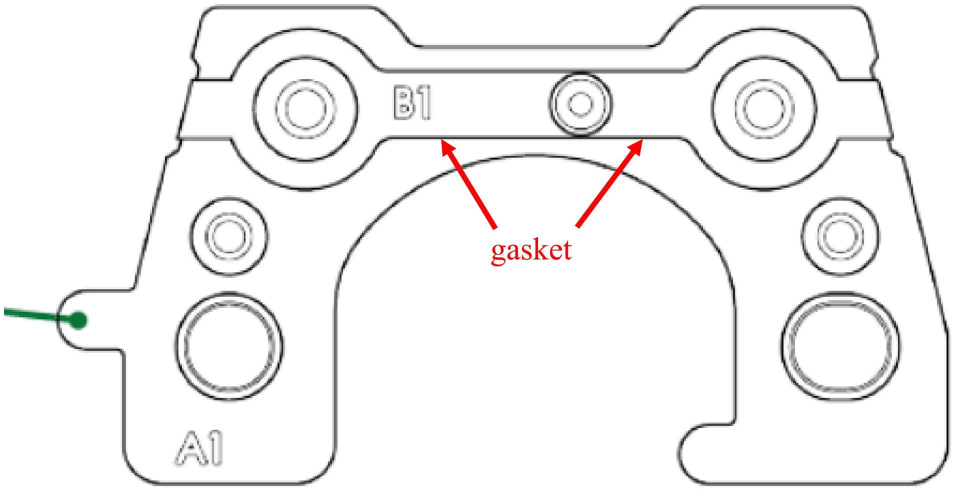
266. "a bracket positioned within the frame, wherein the bracket floats relative to the microfluidic plate and the frame, the bracket comprising." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 231–233), the microfluidic cartridge in the AVITI Systems has a bracket positioned within the frame, wherein the bracket floats relative to the microfluidic plate and the frame. The below image shows the claimed bracket.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

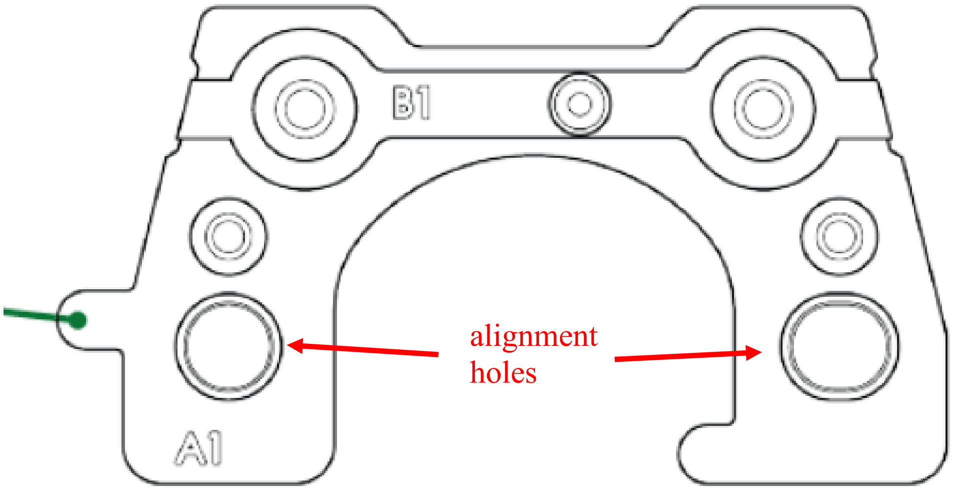
This bracket is positioned within the frame and floats relative to the microfluidic plate, as recited in Claim 1 of the '028 Patent.

267. "a gasket and." The bracket in the AVITI Systems has a gasket as recited in Claim 1 of the '028 Patent. As shown below, the bracket includes a compressible material (marked as "B1"), which is the claimed gasket.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

268. "a plurality of alignment holes." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 238–240), the bracket in the AVITI Systems has a plurality of alignment holes, as shown in the image below. The two holes in the bottom portion of the bracket, which are used to align the seals, are the plurality of alignment holes recited in Claim 1 of the '028 Patent.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

269. "wherein the frame includes a plurality of apertures proximate the first edge of the microfluidic plate; and." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 244–245), the frame in the AVITI Systems has a plurality of apertures proximate the first edge of the microfluidic plate. The two holes in the plastic cartridge (the frame) through which two of the silver pins (the second plurality of indexing features) are inserted are the plurality of apertures recited in Claim 1 of the '028 Patent.

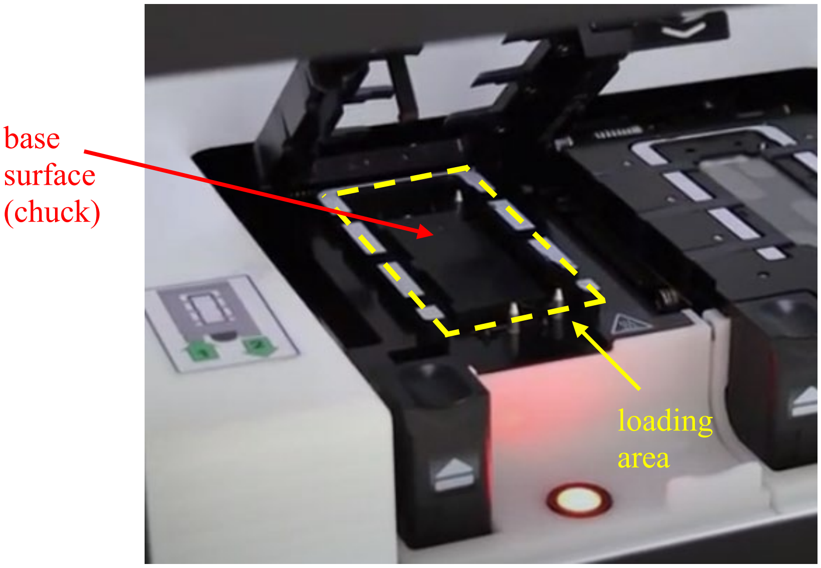
270. "a sequencer with a receiver configured to receive the microfluidic cartridge, the receiver including." As previously alleged in regard to Claim 1 of the '116 Patent (*see supra* ¶¶ 173–175), the AVITI Systems are DNA sequencing instruments. (*See also* Ex. 24, AVITI System Workflow Guide at 6 ("The Element AVITI System is a mid-throughput next-generation sequencing (NGS) system that amplifies and sequences DNA libraries.").) Thus, the AVITI Systems include the sequencer recited in Claim 1 of the '028 Patent.

271. The AVITI Systems' sequencers include a receiver. As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶ 82), each of the AVITI Systems has a nest bay that includes two nests, one for each side. The nests are the receivers of the sequencers recited in Claim 1 of the '028 Patent.

272. In the AVITI Systems, "[e]ach nest holds one flow cell secured with a lid." (Ex. 24, AVITI System Workflow Guide at 13; *see also* Ex. 22,

AVITI24 System User Guide at 8 ("The nest bay includes two nests, one for each side, and each nest holds one flow cell.").) Thus, the receivers are configured to receive the flow cell (microfluidic device) as recited by Claim 1 of the '028 Patent.

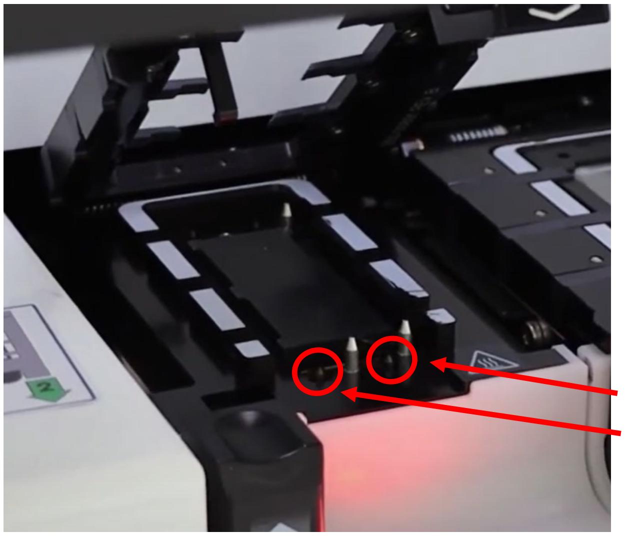
273. "a chuck." The receiver in the AVITI Systems has a chuck as recited in Claim 1 of the '028 Patent. The '028 Patent discloses that the chuck is the component of the receiver "against which the glass plate **114** may be drawn, e.g., by a vacuum, during analysis operations. . . . The ends of the receiver **162** may include, for example, a clamping mechanism that may serve to clamp the glass plate **114** against the chuck **176**." (Ex. 7, '028 Patent at 10:3–13.) The loading region of the AVITI Systems includes a base surface on which the microfluidic cartridge is positioned within the instrument. The base surface is shown in the image below. The base surface is the chuck recited in Claim 1 of the '028 Patent because the flow cell is clamped against the base surface during operation of the AVITI Systems.



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

274. "a plurality of analysis device ports." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 251–252), the AVITI Systems include ports located on an analysis device. The ports on the AVITI Systems (the sequencers) are the plurality of analysis device ports recited in Claim 1 of the '028 Patent.

275. "a first plurality of indexing features corresponding to the plurality of alignment holes; and." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 238–240), the two protrusions on the nest (the receiver) are a first plurality of indexing features, shown in the image below, and as recited in Claim 1 of the '028 Patent. Those protrusions also correspond to the plurality of alignment holes as recited in Claim 1 of the '028 Patent.

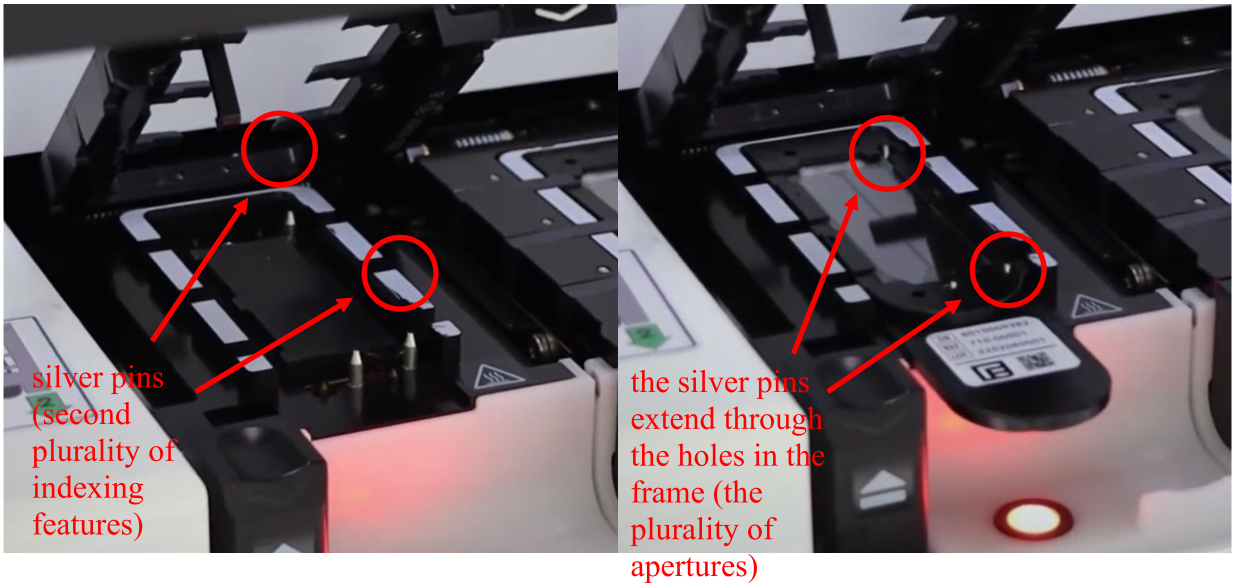


(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

276. When the flow cell (the microfluidic cartridge) is installed in the AVITI Systems, the protrusions on the nest (the first plurality of indexing features) extend into the two alignment holes in the bracket (the plurality of alignment holes) to position the seals. Thus, the protrusions on the nest (the first plurality of indexing features) correspond to the two alignment holes in the bracket (the plurality of alignment holes) as recited in Claim 1 of the '028 Patent.

277. "a second plurality of indexing features corresponding to the plurality of apertures, wherein." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶ 246), two of the three silver pins in the loading area of the nest are a second plurality of indexing features, as recited in Claim 1 of the '028 Patent. Those two silver pins correspond to the plurality of apertures recited in Claim 1 of the '028 Patent.

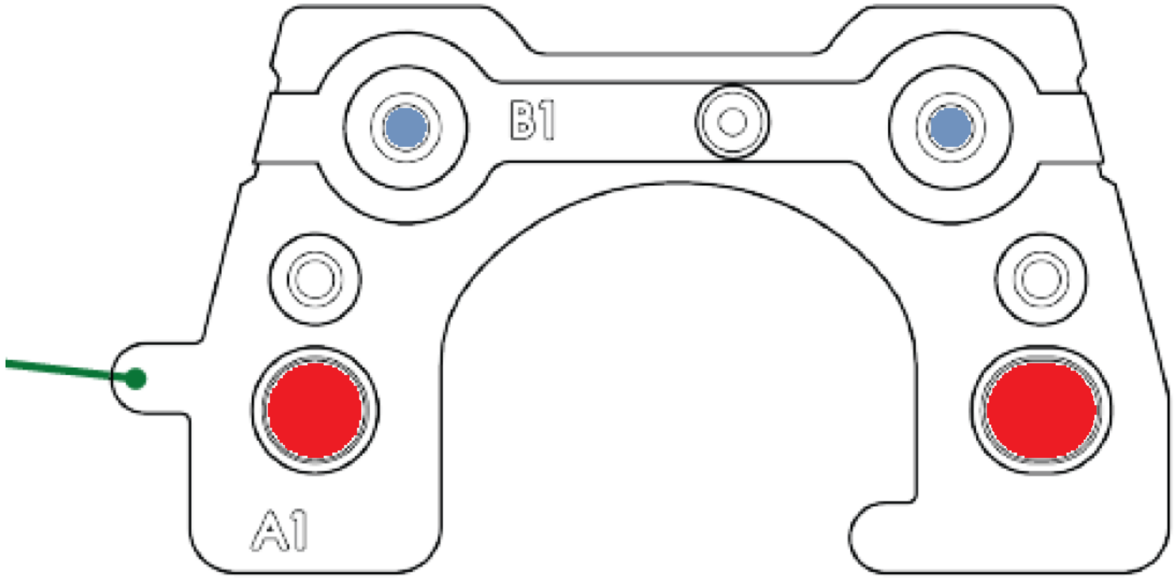
278. The image below shows the two silver pins (the second plurality of indexing features) extending through the two holes in the frame (the plurality of apertures) to position the flow cell (the microfluidic cartridge) on the nest (the receiver). Thus, the two silver pins (the second plurality of indexing features) correspond to the two holes in the frame (the plurality of apertures) as recited in Claim 1 of the '028 Patent.


silver pins (second plurality of indexing features)
the silver pins extend through the holes in the frame (the plurality of apertures)

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

279. "the first plurality of indexing features and the plurality of alignment holes are configured to align the plurality of analysis device ports and the gasket, and." The first plurality of indexing features and the plurality of alignment holes in the AVITI Systems are configured to align the plurality of analysis device ports and the gasket as recited in Claim 1 of the '028 Patent. The

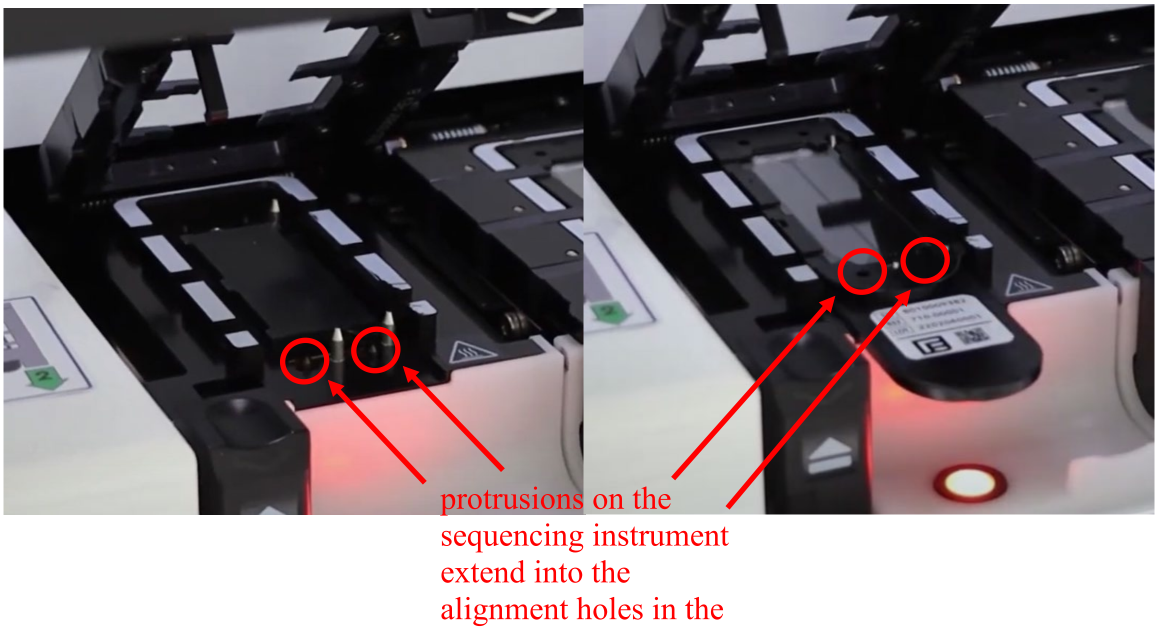
below image of the bracket shows the two holes in the bracket (the plurality of alignment holes) colored in **red** and the two holes in the compressible material (the gasket) colored in **blue**.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red and blue coloring added).)

280. In the AVITI Systems, "[l]ibrary and reagents enter the flow cell through inlet ports and exit as waste through outlet ports." (Ex. 9, AVITI System User Guide at 13; Ex. 22, AVITI24 System User Guide at 13 (same).) When the two protrusions on the nest (the first plurality of indexing features) are inserted into the holes in the bracket (the alignment holes) as shown in the image below, the bracket is positioned such that the reagents flow from the flow cell outlet ports, which are aligned with the gasket, to the AVITI Systems ports (*i.e.*,

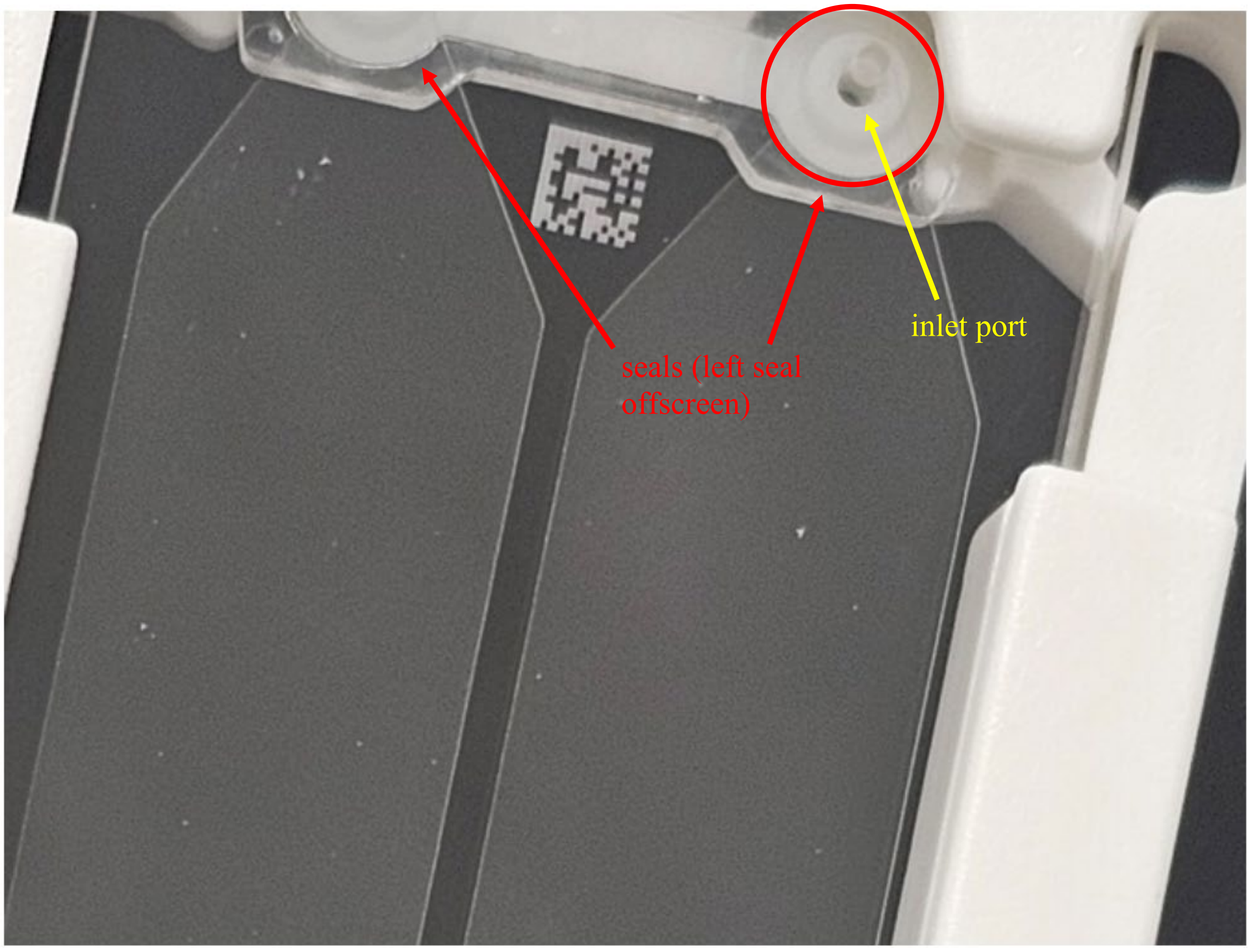
the analysis device ports). Thus, the two protrusions on the nest (the first plurality of indexing features) and the two holes in the support bracket (the plurality of alignment holes) are configured to align the ports on the AVITI sequencer (the plurality of analysis device ports) and the compressible material (the gasket) in the bracket of the flow cell (microfluidic cartridge).



(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

281. "the second plurality of indexing features are configured to engage the microfluidic plate to align the plurality of first fluidic ports and the gasket." In the AVITI Systems, the compressible material on the bracket (the gasket) interfaces with the flow cell outlet ports (the plurality of first fluidic ports) of the flow cell (microfluidic cartridge). The image below shows the flow cell ***inlet*** ports of the flow cell in the AVITI Systems. The relationship between the

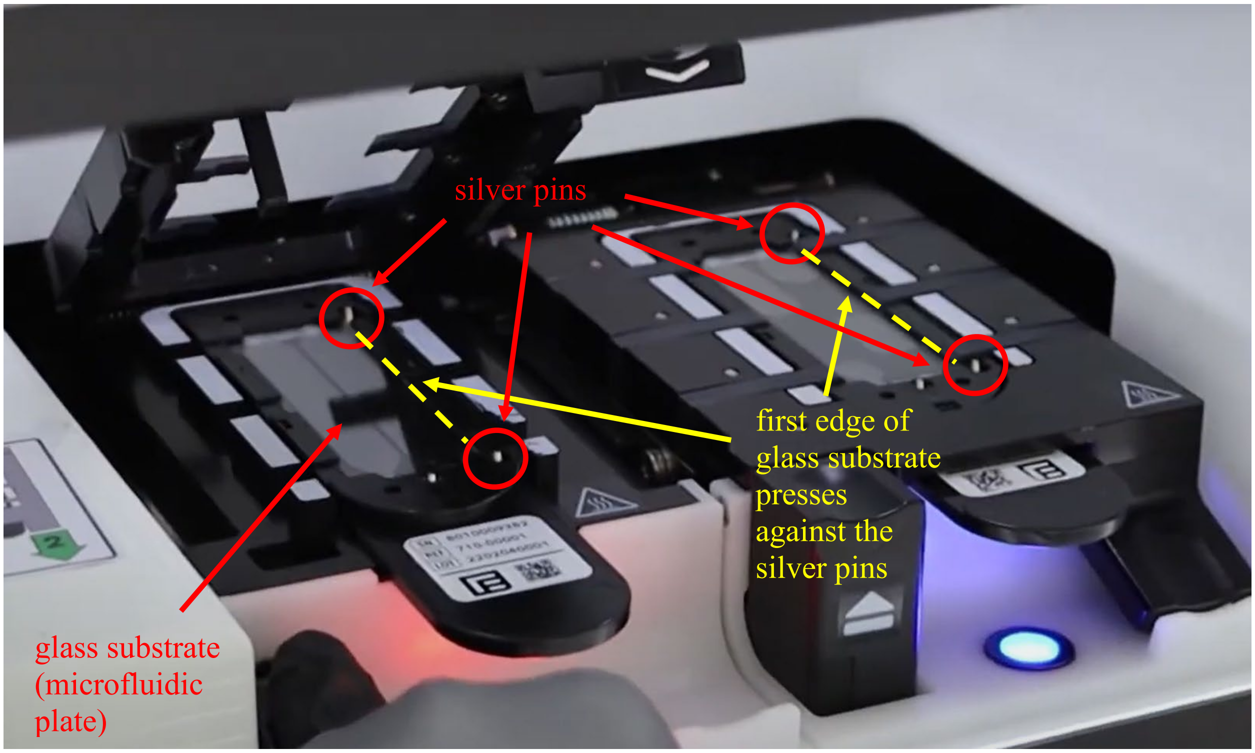
flow cell ***inlet*** ports and the gasket on the bracket that interfaces with the inlet ports is identical to the relationship between the flow cell ***outlet*** ports (the first plurality of fluidic ports) and the gasket on the bracket that interfaces with the ***outlet*** ports.



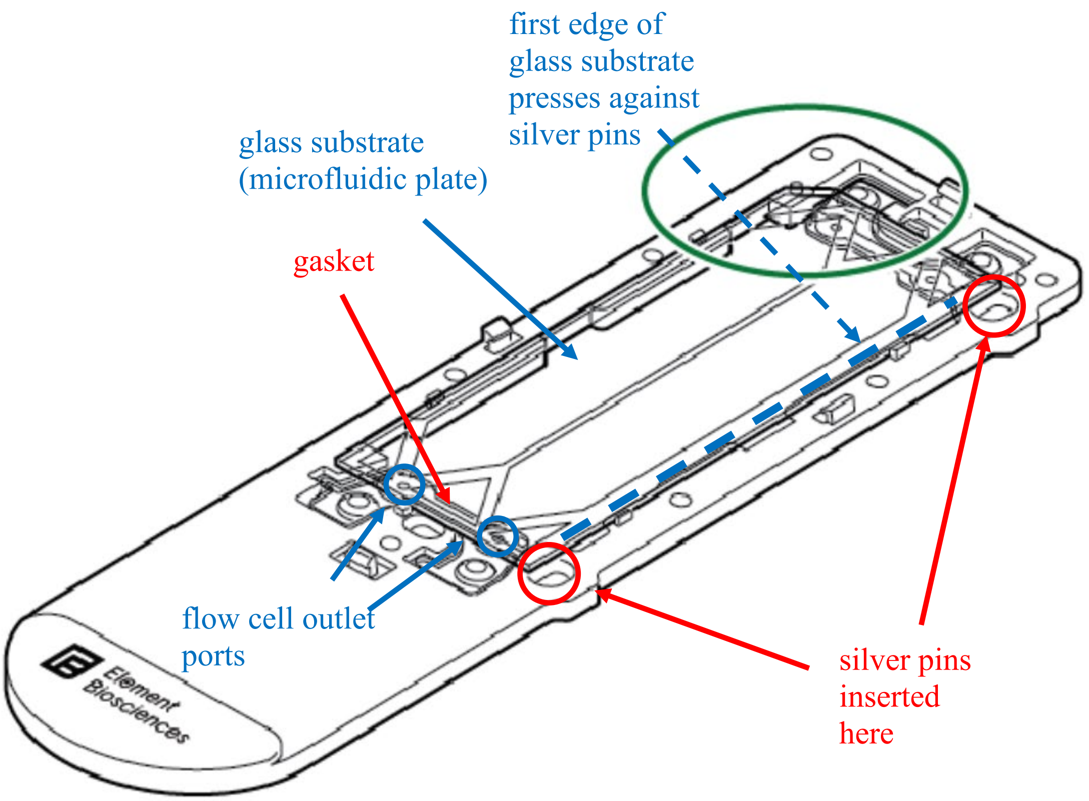
(Ex. 15, Cloudbreak Sequencing User Guide at 28 (annotated).)

282. As shown in the images below, when the microfluidic device is inserted into the nest (the receiver) and the nest lid is closed, the glass substrate (the microfluidic plate) presses against the two silver pins (the second plurality of indexing features). When the glass substrate (the plate) is pressed against the silver pins, the glass substrate is held in a fixed position such that the outlet ports

on the bottom of the flow cell (the plurality of first fluidic ports) are aligned with the gasket in the bracket. Thus, the two silver pins (the second plurality of indexing features) are configured to engage the two-lane glass substrate (the microfluidic plate) to align the flow cell outlet ports (the plurality of first fluidic ports) and the gasket.


silver pins
first edge of glass substrate presses against the silver pins
glass substrate (microfluidic plate)

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 4:56 (July 21, 2022) (annotated).)


first edge of
glass substrate
presses against
silver pins
glass substrate
(microfluidic plate)
gasket
flow cell outlet
ports
silver pins
inserted
here
Element
Biosciences

(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red and blue annotations added).)

283. As shown above, the AVITI Systems satisfy each and every limitation of Claim 1 of the ’028 Patent. The AVITI Systems also satisfy each and every limitation of at least Claims 2–8.

284. In violation of 35 U.S.C. § 271(a), Element has infringed the ’028 Patent by making, using, offering to sell and selling the AVITI Systems.

285. In violation of 35 U.S.C. § 271(b), Element is inducing and will continue to induce its customers to directly infringe, both literally and/or under the doctrine of equivalents, the ’028 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including

on Element's website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element's customers and prospective customers and/or providing technical support or other services for the products to Element's customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the "microfluidic cartridge," and monitoring sequencing metrics (Ex. 24, AVITI System Workflow Guide at 53–54; Ex. 22, AVITI24 System User Guide at 24), thereby making use of the "chemical or biological analysis system." Element knows that when Element's customers use the AVITI Systems as directed by Element, Element's customers are directly infringing the '028 Patent.

286. Element has been on notice of the infringement alleged in this Count since at least on or around June 11, 2025, when Illumina filed an amended complaint alleging that Element infringes the '028 Patent.

287. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

COUNT VII: INFRINGEMENT OF THE '301 PATENT

288. Illumina incorporates by reference paragraphs 1–72 as if fully set forth herein.

289. Element has infringed at least Claim 1 of the '301 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell and selling within the United States the inventions claimed in the '301 Patent.

290. Independent Claim 1 of the '301 Patent recites:

> A chemical or biological analysis system comprising:
>
> a microfluidic cartridge that includes:
>
> a frame;
>
> a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame, the microfluidic plate comprising a plurality of first fluidic ports; and
>
> a support positioned within the frame, wherein the support floats relative to the microfluidic plate and the frame, the support comprising:
>
>> a gasket having a plurality of seals, and
>>
>> a plurality of alignment holes; and
>
> a sequencer with a receiver that includes:
>
>> a chuck;
>>
>> a plurality of analysis device ports;
>>
>> a first plurality of pins configured to extend into the plurality of alignment holes and align the plurality of analysis device ports and the plurality of seals; and

> a second plurality of pins configured to engage the microfluidic plate such that the plurality of first fluidic ports and the plurality of seals are aligned, wherein each seal of the plurality of seals has a through-hole passing through the seal to fluidically connect the plurality of first fluidic ports to the analysis device ports.

(Ex. 8, ’301 Patent at 14:10–34.)

291. “A chemical or biological analysis system comprising.” As previously alleged in regard to Claim 1 of the ’028 Patent (*see supra* ¶ 261), the AVITI Systems are chemical or biological analysis systems as recited in Claim 1 of the ’301 Patent. (*See* Ex. 24, AVITI System Workflow Guide at 6 (“The Element AVITI System is a mid-throughput next-generation sequencing (NGS) system that amplifies and sequences DNA libraries.”); Ex. 22, AVITI24 System User Guide at 6 (“The AVITI24 System measures a diverse array of molecular features for deep multiomic profiling of RNA, protein, and morphology in a single sample in 24 hours.”).)

292. “a microfluidic cartridge that includes.” As previously alleged in regard to Claim 1 of the ’702 Patent (*see supra* ¶ 224) and Claim 1 of the ’028 Patent (*see supra* ¶ 262), the AVITI Systems include a flow cell and a plastic cartridge. Together, the flow cell and plastic cartridge comprise the microfluidic cartridge recited in Claim 1 of the ’301 Patent.

293. “a frame.” As previously alleged in regard to Claim 1 of the ’702 Patent (*see supra* ¶ 225) and Claim 1 of the ’028 Patent (*see supra* ¶ 263), the

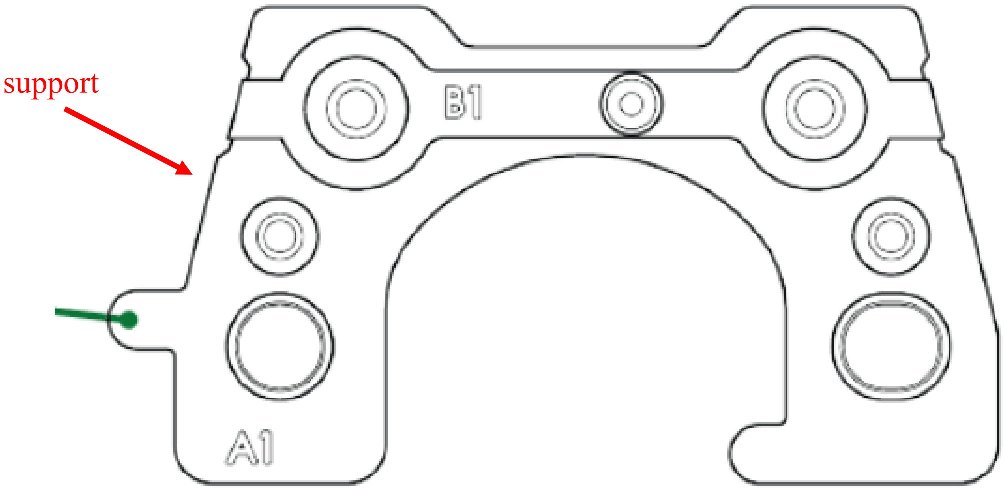
microfluidic cartridge in the AVITI Systems includes a plastic cartridge. The plastic cartridge of the microfluidic cartridge is the frame recited in Claim 1 of the '301 Patent.

294. "a microfluidic plate positioned within the frame, wherein the microfluidic plate floats relative to the frame." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 226–227) and Claim 1 of the '028 Patent (*see supra* ¶ 264), the microfluidic cartridge in the AVITI Systems has a glass substrate positioned within the frame that floats relative to the frame. This glass substrate is the floating microfluidic plate recited in Claim 1 of the '301 Patent.

295. "the microfluidic plate comprising a plurality of first fluidic ports; and." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 228–230) and Claim 1 of the '028 Patent (*see supra* ¶ 265), the microfluidic plate in the AVITI Systems has a plurality of first fluidic ports as recited in Claim 1 of the '301 Patent. In the AVITI Systems, the flow cell outlet ports that are located on the bottom face of the glass substrate are the plurality of first fluidic ports. These are the first fluidic ports recited in Claim 1 of the '301 Patent.

296. "a support positioned within the frame, wherein the support floats relative to the microfluidic plate and the frame, the support comprising." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 231–233),

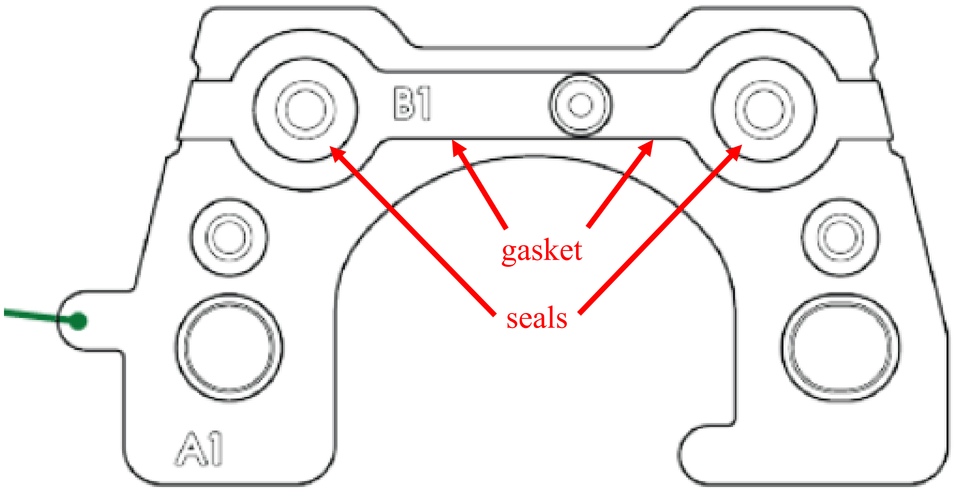
the microfluidic cartridge in the AVITI Systems has a support —referred to as a support bracket in Claim 1 of the ’702 Patent—positioned within the frame, wherein the support floats relative to the microfluidic plate and the frame. The below image shows the claimed support.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

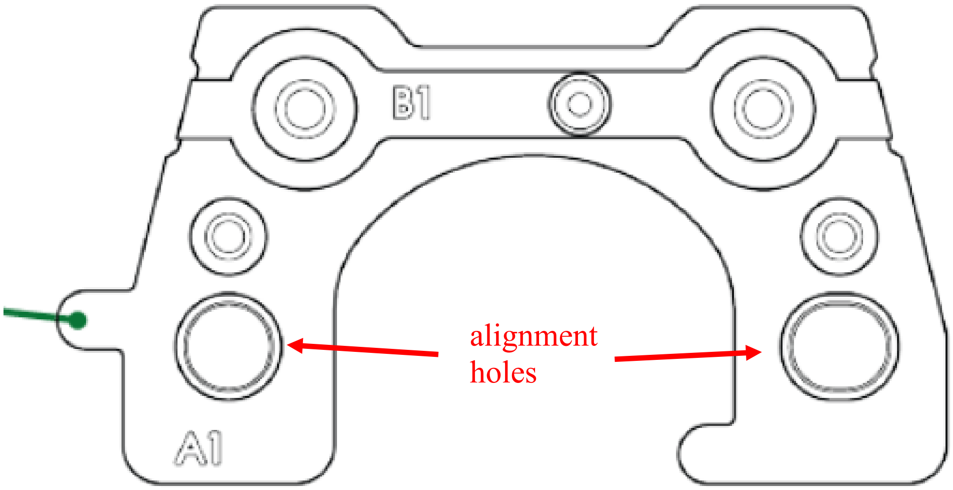
This support is positioned within the frame and floats relative to the microfluidic plate and the frame, as recited in Claim 1 of the ’301 Patent.

297. “a gasket having a plurality of seals, and.” As previously alleged in regard to Claim 1 of the ’028 Patent (*see supra* ¶ 267), the support in the AVITI Systems—referred to as a bracket in Claim 1 of the ’028 Patent—has a gasket as recited in Claim 1 of the ’301 Patent. As shown below, the support includes a compressible material (marked as “B1”), which is the claimed gasket, and the gasket has two seals (that is, a plurality of seals), as recited in Claim 1 of the ’301 Patent.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

298. "a plurality of alignment holes." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 238–240) and Claim 1 of the '028 Patent (*see supra* ¶ 268), the support in the AVITI Systems—referred to as the support bracket or bracket in the '702 and '028 Patents, respectively—has a plurality of alignment holes, as shown in the image below. The two holes in the bottom portion of the support, which are used to align the seals, are the plurality of alignment holes recited in Claim 1 of the '301 Patent.

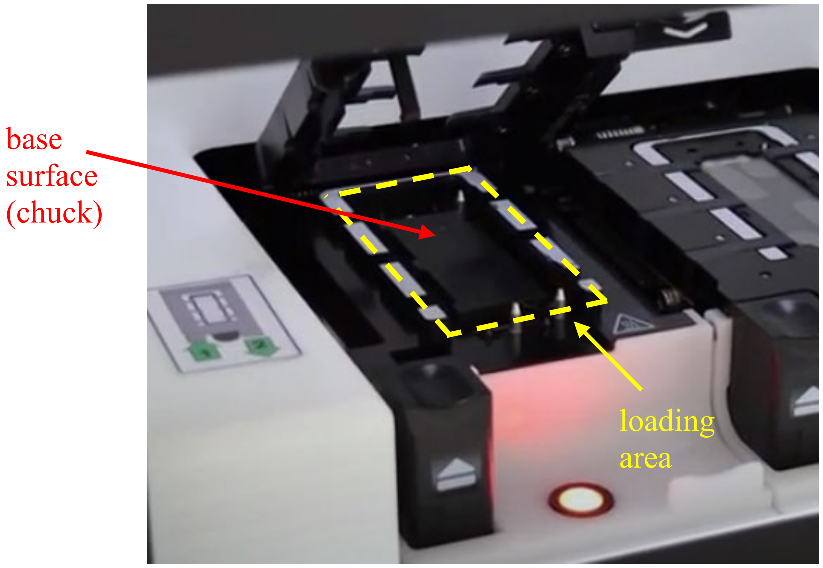


(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red annotations added).)

299. "a sequencer with a receiver that includes." As previously alleged in regard to Claim 1 of the '116 Patent (*see supra* ¶¶ 173–175) and Claim 1 of the '028 Patent (*see supra* ¶ 270), the AVITI Systems are DNA sequencing instruments. (*See also* Ex. 24, AVITI System Workflow Guide at 6 ("The Element AVITI System is a mid-throughput next-generation sequencing (NGS) system that amplifies and sequences DNA libraries.").) Thus, the AVITI Systems include the sequencer recited in Claim 1 of the '301 Patent.

300. The AVITI Systems' sequencers include a receiver. As previously alleged in regard to Claim 1 of the '241 Patent (*see supra* ¶ 82) and Claim 1 of the '028 Patent (*see supra* ¶ 271), each of the AVITI Systems has a nest bay that includes two nests, one for each side. The nests are the receivers of the sequencers recited in Claim 1 of the '301 Patent.

301. "a chuck." As previously alleged in regard to Claim 1 of the '028 Patent (*see supra* ¶ 273), each of the AVITI Systems has a chuck, as recited in Claim 1 of the '301 Patent. The base surface shown in the image below is the chuck recited in Claim 1 of the '301 Patent.

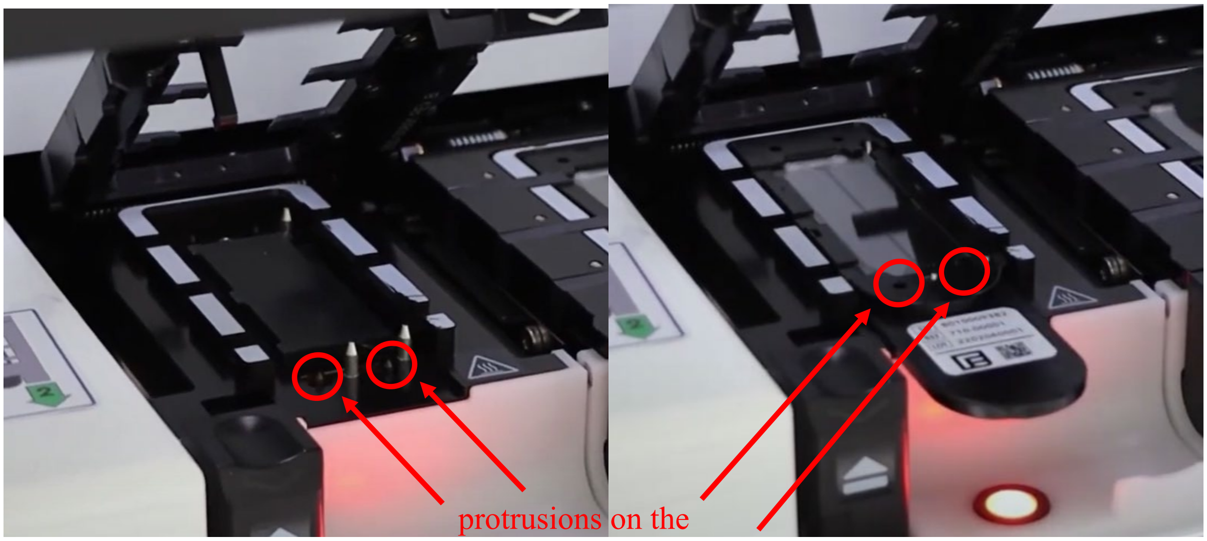


(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01 (July 21, 2022) (annotated).)

302. "a plurality of analysis device ports." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 251–252) and Claim 1 of the '028 Patent (*see supra* ¶ 274), the AVITI Systems include ports located on an analysis system. The ports on the AVITI Systems (the sequencers) are the plurality of analysis device ports recited in Claim 1 of the '301 Patent.

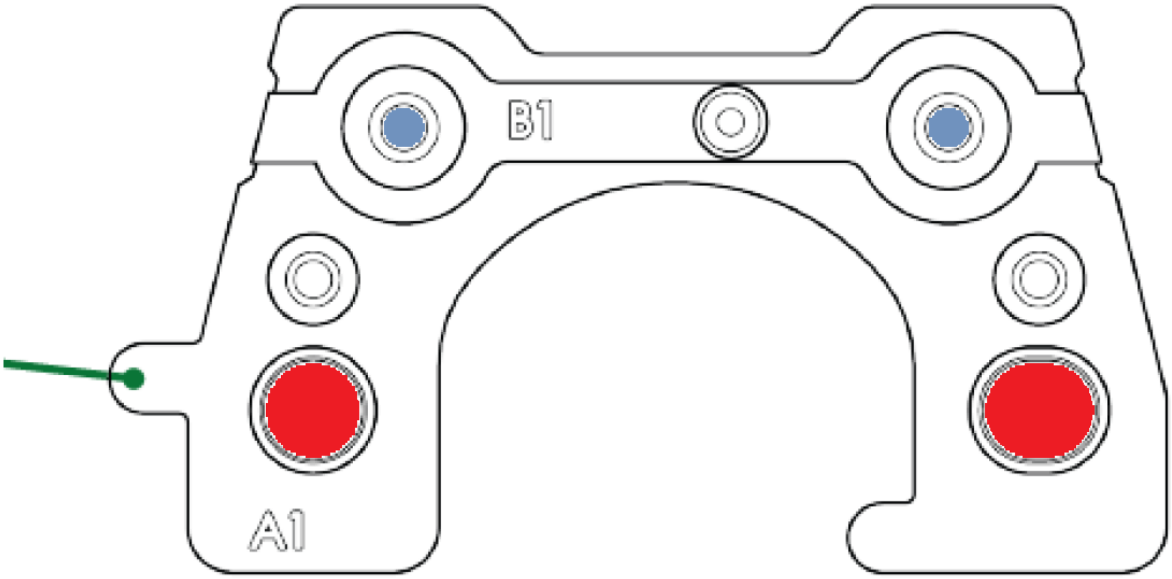
303. "a first plurality of pins configured to extend into the plurality of alignment holes and align the plurality of analysis device ports and the plurality of seals; and." As previously alleged in regard to Claim 1 of the '702 Patent (*see*

supra ¶¶ 238–243) and Claim 1 of the '028 Patent (*see supra* ¶¶ 275–276), when the microfluidic cartridge is installed in the AVITI Systems, the protrusions (here, the first plurality of pins) extend into two alignment holes (the plurality of alignment holes) in the support to align the AVITI Systems ports (the analysis device ports) with the seals on the support (the plurality of seals), as recited in Claim 1 of the '301 Patent.


protrusions on the
sequencing instrument
extend into the alignment
holes in the support

(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 5:01, 5:05 (July 21, 2022) (annotated).)

304. The below image of the support shows the two holes in the support (the plurality of alignment holes) colored in **red** and the two seal holes colored in **blue**.



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red and blue coloring added).

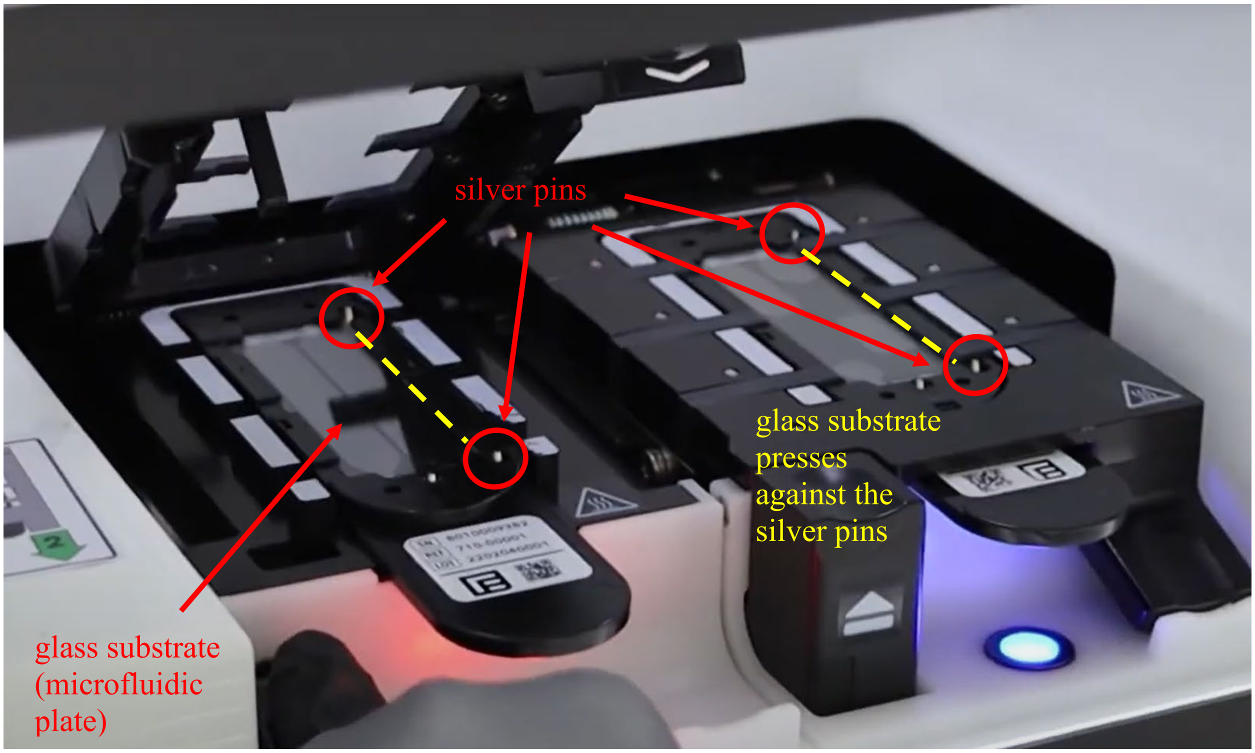
305. When the protrusions on the receiver of the sequencer (the first plurality of pins) are inserted into the alignment holes in the support (the plurality of alignment holes), the support is positioned such that the seals on the support (the plurality of seals) align with the AVITI Systems ports (the analysis device ports).

306. "a second plurality of pins configured to engage the microfluidic plate such that the plurality of first fluidic ports and the plurality of seals are aligned." As previously alleged in regard to Claim 1 of the '702 Patent (*see supra* ¶¶ 228–230), the flow cell outlet ports on the support are the plurality of the first fluidic ports of the AVITI Systems, as recited in Claim 1 of the '301 Patent. As previously alleged in regard to Claim 1 of the '702 Patent (*see supra*

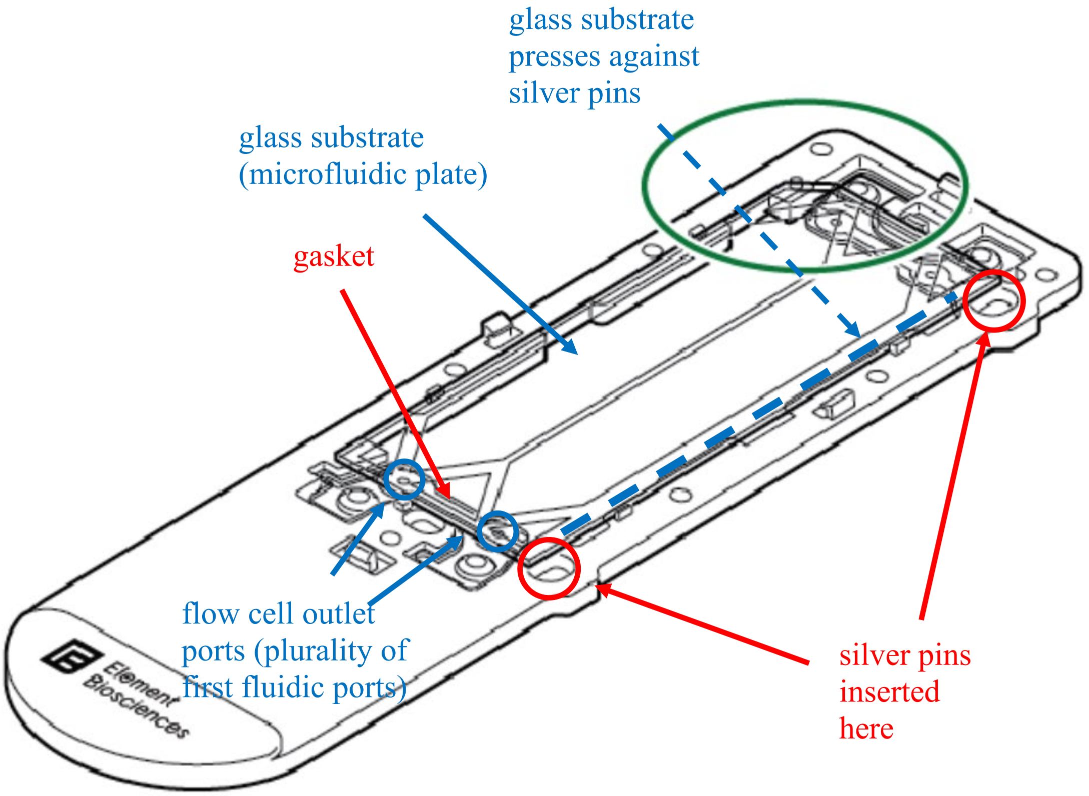
¶¶ 246–248), when the microfluidic cartridge is installed in the AVITI Systems, two of the three silver pins (the second plurality of pins) are configured to extend through two holes in the frame of the microfluidic cartridge to engage the glass substrate (the microfluidic plate) such that the flow cell outlet ports (the plurality of first fluidic ports) are aligned with the seals on the support (the plurality of seals), as recited in Claim 1 of the ’301 Patent.

307. As shown in the images below, when the flow cell (microfluidic cartridge) is inserted into the nest (the receiver) and the nest lid is closed, the glass substrate (the microfluidic plate) presses against the two silver pins (the second plurality of pins). When the glass substrate (the plate) is pressed against the silver pins, the glass substrate is held in a fixed position such that the outlet ports on the bottom of the flow cell (the plurality of first fluidic ports) are aligned with the seals in the support. Thus, the two silver pins (the second plurality of pins) are configured to engage the two-lane glass substrate (the microfluidic plate) such that the flow cell outlet ports (the plurality of first fluidic ports) and the seals on the support (the plurality of seals) are aligned. (*See* Ex. 24, AVITI System Workflow Guide at 52 (directing the user to load the flow cell and plastic cartridge into the nest by “plac[ing] the flow cell over the three registration pins on the nest”); *see also* Ex. 22, AVITI24 System User Guide at 8 (“To ensure proper alignment, three

silver pins on the loading area fit into three corresponding holes on the flow cell cartridge.").)


silver pins
glass substrate presses against the silver pins
glass substrate (microfluidic plate)

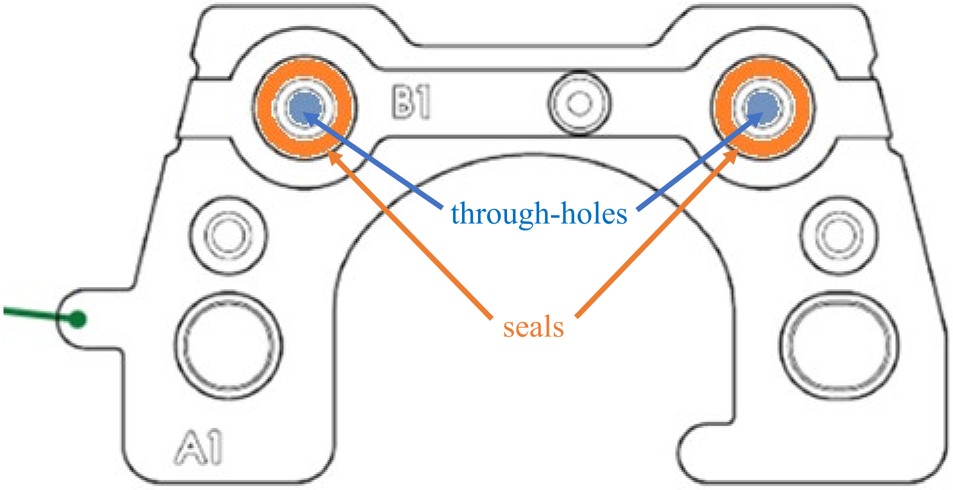
(Ex. 26, "Element AVITI™ System - Instrument Demonstration," https://www.youtube.com/watch?v=2Q4DQV9H80U at 4:56 (July 21, 2022) (annotated).)


glass substrate
presses against
silver pins
glass substrate
(microfluidic plate)
gasket
flow cell outlet
ports (plurality of
first fluidic ports)
silver pins
inserted
here
Element
Biosciences

(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, red and blue annotations added).) (Seals are not visible in this image.)

308. "wherein each seal of the plurality of seals has a through-hole passing through the seal to fluidically connect the plurality of first fluidic ports to the analysis device ports." In the AVITI Systems, each seal has a through-hole passing through the seal to fluidically connect plurality of first fluidic ports to the analysis device ports, as recited in Claim 1 of the '301 Patent.

309. The below image of the support shows a hole in each of the seals in the support (the through-holes colored in **blue** passing through the seal colored in **orange**).



(Ex. 20, Teton CytoProfiling User Guide at 25 (green annotation in original, orange and blue coloring added).)

310. When the microfluidic cartridge is inserted in the sequencer, the protrusions (the first plurality of pins) extend into the two alignment holes in the support (the plurality of alignment holes), and at least two of the three silver pins (the second plurality of pins) are configured to engage the glass substrate (the microfluidic plate) through the holes in the frame of the microfluidic cartridge. This aligns the flow cell outlet ports (the plurality of first fluidic ports), the seals on the support (the plurality of seals) and the sequencer ports (the analysis device ports).

311. In the AVITI Systems, "[l]ibrary and reagents enter the flow cell through inlet ports and exit as waste through outlet ports." (Ex. 9, AVITI System User Guide at 13; Ex. 22, AVITI24 System User Guide at 13 (same).) The through-holes allow the library and the reagents to flow as waste from the outlet

ports (the plurality of first fluidic ports) to the sequencer ports (the analysis device ports).

312. As shown above, the AVITI Systems satisfy each and every limitation of Claim 1 of the '301 Patent.

313. In violation of 35 U.S.C. § 271(a), Element has infringed the '301 Patent by making, using, offering to sell and selling the AVITI Systems.

314. In violation of 35 U.S.C. § 271(b), Element is inducing and will continue to induce its customers to directly infringe, both literally and/or under the doctrine of equivalents, the '301 Patent by taking actions that include, but are not limited to, advertising its products and services and their infringing uses, including on Element's website; establishing distribution channels for these products in the United States; drafting, distributing or making available product specifications, instructions or user manuals for the products to Element's customers and prospective customers and/or providing technical support or other services for the products to Element's customers and prospective customers. For example, the AVITI product guides direct the user to perform infringing uses of the AVITI Systems, including loading a flow cell into the nest (Ex. 24, AVITI System Workflow Guide at 52; Ex. 22, AVITI24 System User Guide at 8), thereby making use of the "microfluidic cartridge," and monitoring sequencing metrics (Ex. 24, AVITI System Workflow Guide at 53–54; Ex. 22, AVITI24 System User Guide at

24), thereby making use of the "chemical or biological analysis system." Element knows that when Element's customers use the AVITI Systems as directed by Element, Element's customers are directly infringing the '301 Patent.

315. Element has been on notice of the infringement alleged in this Count since at least on or around August 26, 2025, when the '301 Patent issued and Illumina shared its proposed second amended complaint with Element alleging that it infringes the '301 Patent.

316. Illumina has been damaged by the infringement alleged in this Count and will suffer irreparable harm absent an injunction.

PRAYER FOR RELIEF

WHEREFORE, Illumina prays for judgment in its favor and against Element and respectfully requests the following relief:

A. A judgment that Element has infringed one or more claims of the '241 Patent, the '781 Patent, the '130 Patent, the '116 Patent, the '702 Patent, the '028 Patent and the '301 Patent.

B. Damages adequate to compensate Illumina for the infringement, but in no event less than a reasonable royalty for the use made of the inventions by Element, together with interest and costs.

C. Enhanced damages up to three times the amount found or assessed for the infringement of the '241 Patent, the '781 Patent, the '130 Patent, and the ’116 Patent pursuant to 35 U.S.C. § 284 on the ground that Element’s infringement of those patents was and is deliberate and willful.

D. An injunction against infringement of the ’241 Patent, the ’781 Patent, the ’130 Patent, the ’116 Patent, the ’702 Patent, the ’028 Patent and the ’301 Patent.

E. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285, and awarding reasonable attorneys’ fees, costs and disbursement incurred as a result of this action.

F. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Illumina demands a jury trial on all issues so triable.

/s/ Kelly E. Farnan

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